PART 6

EXHIBITS TO DECLARATION OF SARAH BLAINE

EXHIBIT 14

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
DOCKET NO. 07-CV-359

CHAYA GROSSBAUM and MENACHEM GROSSBAUM, her spouse, individually, as guardians ad litem of the infant, ROSIE GROSSBAUM, Plaintiffs, v. GENESIS GENETICS INSTITUTE, L.L.C., of the State of Michigan, MARK R. HUGHES, M.D., NEW YORK UNIVERSITY SCHOOL OF MEDICINE and NEW YORK UNIVERSITY HOSPITALS CENTER, both corporations in the State of New York, ABC CORPORATIONS 1-10 and JOHN DOE 1-10,	DEPOSITION OF: ALEXIS ADLER

T R A N S C R I P T of the stenographic notes of the proceedings in the above-titled matter, as taken by PHILIP A. FISHMAN, a Certified Shorthand Reporter and Notary Public of the State of New Jersey, held at the offices of the NYU School of Medicine, 660 First Avenue, New York, New York, on Monday, July 13, 2009, commencing at 4:00 in the afternoon.

PHILIP A. FISHMAN
COURT REPORTING AGENCY
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A P P E A R A N C E S :

NUSBAUM, STEIN, GOLDSTEIN, BRONSTEIN & KRON, ESQS.
BY: LEWIS STEIN, ESQ.
Appearing on behalf of the Plaintiffs

STEPHEN N. LEUCHTMAN, P.C.
BY: STEPHEN N. LEUCHTMAN, ESQ.
Appearing on behalf of the Defendant Genesis Genetics Institute, L.L.C., and Dr. Hughes

MARSHALL, DENNEHEY, WARNER, COLEMAN & GOGGIN, ESQS.
BY: JAMELE A. HAMAD, ESQ.
Appearing on behalf of the Defendants New York University School of Medicine and New York University Hospitals Center

* * *

Q. Is there any type of sedation given to the patient during implantation?

A. At times anesthesia is required.

At times Valium is given.

Q. And when you say "anesthesia is required," does that require an anesthesiologist to be present?

A. Yes.

Q. Okay. Can you tell me from the chart whether an anesthesiologist was present at the time of implantation here?

A. Seemingly not.

Q. Have you ever had occasion to talk to Dr. Hughes about his reports on any patient once you received them?

A. Sometimes.

Q. And what would be the purpose of your calling or speaking with Dr. Hughes?

A. To discuss the report.

Q. And what aspect of the report would you discuss?

A. The results.

Q. Okay. Well, if you give the report to the doctor, why would you be discussing his report?

A. Just to get clarification.

Q. Okay. Do you recall whether clarification was required in connection with the report of Genesis Genetics regarding the Grossbaums?

A. I don't recall.

Q. Okay. If you do have a conversation with Dr. Hughes in connection with any patient, seeking a clarification, do you make a chart entry under normal circumstances?

A. Yes.

Q. Okay. The fact that there is no indication that you had any conversations with Dr. Hughes regarding the Grossbaums, does that indicate that there was no need for clarification of the report received regarding the Grossbaums?

MR. HAMAD: Objection to form.

You can answer.

A. I don't recall.

Q. Okay. If your only interest -- withdraw that.

If your only involvement in the implantation process is the assessment of the embryos for implantation, what would your involvement be with respect to the Genesis Genetics report?

MR. HAMAD: Objection; asked and answered.

You can answer it again.

A. I am not sure what you are saying.

Q. Well, you have indicated in your prior testimony, according to what I understand, is that your only involvement in implantation is to assess the embryos and

EXHIBIT 15

VOLUME II

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW JERSEY

CHAYA GROSSBAUM and MENCHEN GROSSBAUM, Her Spouse, Individually, and as Guardians ad litem of the Infant, ROSIE GROSSBAUM

Plaintiffs

vs.

GENESIS GENETICS INSTITUTE, LLC, OF THE STATE OF MICHIGAN, MARK R. HUGHES, M.D., NEW YORK UNIVERSITY SCHOOL OF MEDICINE and NEW YORK UNIVERSITY HOSPITALS CENTER, Both Corporations of the State of New York, ABC CORPORATIONS: 1-10 and John Doe

Defendants

Certified Transcript

Docket No. 07-CV-359

GARRY CUTTING, M.D.

November 8, 2010

REPORTED BY: Dawn L. Venker

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A Between --
(The reporter made a statement.)
Q Doctor, I like you to do the analysis for level of risk for having an afflicted child based on Embryo Number 7, assuming that the laboratory that produced these results --
A Okay.
Q -- which --
A 0.5 times --
Q -- assuming that the laboratory that produced these results --
A Yes.
Q -- has an ADO -- A-D, as in David, O -- rate of 5 to 10 percent --
A 5 to 10 percent. Yes.
Q -- what would the risk be for Embryo Number 7?
A 2.5 to 5 percent.
Q Okay. Now, do the same analysis, please, for Embryo Number 8?
A For Embryo Number --
Q Well, let's look at it together. What's the value for the --
A You just asked me to do the analysis for Embryo 8.

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Q I strike the question.
A I'm sorry. You were continuing.
Q Bad question. Bad question.
A Okay. I'm sorry.
Q I'll ask you a better question. Let's look at Embryo Number 8. You got it in front of you there?
A Yeah.
Q All right. What's the value for the paternal mutation there? What do we have?
A The value for the paternal mutation on Number 8?
Q Well, what's the result, let's just look at the result.
A The result says "no deletion detected."
Q Okay. "No deletion" means what?
(The reporter asked for clarification.)
Q No. No deletion.
A No deletion.
Q Yeah.
A No abnormal mutation found.
Q So that carries an ADO risk, Allele dropout risk?
A Very small.
Q Okay. Well, if the laboratory is 5 to 10 percent, it's 5 to 10 --

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A No, it's not.
Q Okay.
A No, it's not. As I tried to explain to you before, which you are missing, is that you have detected the presence -- ADO is the inability to detect the presence of both parental strains. The second mutation identified in 8 is GT. That means the G must have come from the father, and the T, because the mother carries the mutation. That must come from the mother. So both strains of DNA have to be in that chute (sic) for analysis. So the chance for ADO at this point is actually much lower than the normal rate of ADO because a substitute, though imperfect test, has been done for ADO.
So that is what it -- and you -- I can actually show you this in other ways if you wish. Certainly, I will use this with the jury when it comes around of how you make this estimate.
So the risk here if you want to -- you want to finish my question and -- I'll finish my answer is -- so that we can get through this. We know that it says "no deletion." And we can trust that because it's probably quite rightly likely to be correct because both parental mutate -- mother's mutation -- the mother's mutation was seen here, and the father's

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Allele was seen here. So you know both strands were in there. So ADO is of a low chance of making an error in 8 and in 10.
Q Okay. Let's do it this way, Doctor. Again, I think you -- you have this issue. Please just answer my question.
A Yes. Go ahead.
Q Just the way I ask it, specifically --
A Specifically to your question.
Q -- to my question. Okay?
A Please. Yeah.
Q Because I need the answers. Okay. So let's do it like this. Number 8. All right.
A Yeah. Go ahead.
Q You have the value for the father, right? It says "no deletion."
A Yes.
Q Okay. What percent of risk does that carry? You said 50 percent where there is no amplification --
(The reporter asked for clarification.)
Q We said 50 percent for no amplification.
A Which one? Are we back on Embryo --
Q We said 50 percent for no amplification. Now, what risk do we have for no deletion?

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A I'm missing you.
Q Number -- Number 7 has no amplification.
A That's correct.
Q It was 50 percent.
A That's correct.
Q Number 8 has no deletion. I'm asking you what's the value for no deletion?
A What's the value for no deletion?
Q Yeah.
A The risk of the mutant Allele being there, nearly zero.
Q Nearly? What does "nearly zero" mean?
A Well --
Q 2 percent? 5 percent?
A By itself, the risk -- the underlying -- if there were no other information -- well, there is information. I can't -- so the information is that both parental alleles are here based on the CF11. And the fact that there is no deletion detected means it's unlikely that ADO has occurred in this case. So this is probably a correct call. This is an unaffected fetus.
Q Hmmm.
A Highly likely.
MR. LEUCHTMAN: Which one, sir?

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THE WITNESS: Number 8. As well as 10.
Q Now, if Doctor -- assuming that Dr. Stromme took the opinion that Number 8 was actually more likely to be affected than Number 7 --
A He's wrong --
Q -- you would disagree with him?
A He's wrong.
Q He's wrong. Dr. Hughes took the same opinion or similar opinion.
A Oh, I don't think Dr. Hughes said that because he actually said carry maternal.
Q Well -- but if -- if he did?
A Yeah. They are wrong.
Q They are wrong. Kang Pu, if he did?
A Wrong.
Q Okay. How many reports like this do you -- do you auth -- do you produce?
A Reports like this for linkage?
Q Yeah. How many --
A Oh, yes. I used to do linkage all the time in my laboratory.
Q It's C -- CF --
A DNA diagnostic --
Q Excuse me. Let me finish my question.
(The reporter made a statement.)

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Q Do me a favor. Just answer my questions and don't cut me off. Okay.
A I apologize.
Q All right. Now, how many reports like that one you are looking at right now, the one that's dated July 19th, 2004, have you produced to IVF centers who have parents that they want to implant with embryos based upon your report?
A Based on PGD alone and not other cases of prenatal diagnosis where the same type techniques are used are you saying?
Q Yeah.
A PDG, two cases. In cases of other similar diagnosis --
Q I didn't ask you the other similar --
A Hundreds of cases. Hundreds if not thousands.
Q Okay. All right.
A We developed the markers for these kinds of tests for this gene.
Q You develop the marker, but you don't do the actual testing?
A Oh, we -- not for PGD, no.
Q Oh, oky. All right. So you don't do the testing that is done by Dr. Hughes, right?

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A So I -- do you mean I can't interpret it?
Q I'm not -- just answer my questions.
A Okay.
Q You don't do the testing done by Dr. Hughes, right?
A Yes, I do. I do a PGD. I have done a couple of cases with CF using -- using linked markers as --
Q Do you know how many cases Dr. Hughes does?
A Doesn't matter.
Q Do you know how many cases Dr. Stromme did in his career?
A Probably hundreds.
Q And you did two?
A Yeah. So what?
Q Okay. Dr. Hughes may have done thousands?
A I have no idea how many he has done.
Q And you did two? Dr. Kang Pu, do you know how many he has done?
A No.
Q Okay. And you feel comfortable disagreeing with all these --
A Absolutely. Absolutely.
MR. HAMAD: I have no further question. Thank you.

EXHIBIT 16

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
DOCKET NO. 07-cv-1359

CHAYA GROSSBAUM and MENACHEM GROSSBAUM, her spouse, individually, as guardians ad litem of the infant, ROSIE GROSSBAUM,

Plaintiffs,

v.

GENESIS GENETICS INSTITUTE, LLC, of the State of Michigan MARK R. HUGHES, MD, NEW YORK UNIVERSITY SCHOOL OF MEDICINE and NEW YORK UNIVERSITY HOSPITALS CENTER, both Corporations in the State of New York, ABC Corporations 1-10 and JOHN DOE 1-10,

Defendants.

DEPOSITION OF:
DR. KANGPU XU

TRANSCRIPT of testimony taken Stenographically by and before PHILIP A. FISHMAN, a Certified Shorthand Reporter and Notary Public of the State of New Jersey, at the offices of LOWENSTEIN, SANDLER, ESQS., 1251 Avenue of the Americas, New York, New York on Thursday, May 13, 2010, commencing at three o'clock in the afternoon.

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425 Eagle Rock Avenue
Roseland, New Jersey

BY: JAMELE A. HAMAD, ESQ.
Appearing on behalf of New York University School of Medicine and New York University Hospitals Center.

KANGPU XU,

1300 York Avenue, New York, New York, having been duly sworn according to law, testifies under oath as follows:

DIRECT-EXAMINATION BY MR. STEIN:

Q. Good morning, Dr. Xu.

A. Good morning.

Q. Am I pronouncing your name correctly?

A. Very accurately.

Q. We are here today to take your deposition, which is merely a multi syllable word to describe a question and answer session in which I am going to ask you some questions and your answers and my questions are going to be recorded by the gentleman who sits to my left and your right, who is a Certified Shorthand Reporter.

At the end a booklet, a transcript of your answers and my questions will be prepared for use in this litigation.

To that end, I would like to give you a couple of instructions.

A. Okay.

Q. One, it is not unlikely during this question and answer session that I will ask you a question that makes no sense to a specialist in genetics, since I am, needless to say, not trained in that specialty, so if I

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I don't think we send at that time to RGI yet, but I have to check our record.

Q. Well, whether you were sending them there or not, from your meetings and from your awareness of what they were publishing by way of analysis in 2000, did you not assume they were doing it for those mutations based on the literature and based on their Atlas and the information that they published?

A. I think they publish the workers it's usually the leading -- leading centers '01 of these studies, but to implement it takes time.

For example, I just -- if you allow me -- people started to using micro array technology to detect 24 chromosomes and it's proposed a few years ago, but still in the process of not every lab is using that technology. They already show in the publication you can detect 24 chromosomes, but very few labs are doing it now offering for clinical use, so from the publication to clinical use it takes some time to implement.

Q. Now, Doctor, let's turn to the report that Genesis Genetics sent to NYU.

Do you have a copy of it?

A. Yes, I have.

Q. In his report Dr. Hughes said that sample No. 8

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was okay for transfer. Is that correct?

A. Yes.

Q. And No. 10 was okay for transfer. Is that correct?

A. Yes.

Q. He did not indicate that any of the others were okay for transfer?

MR. HAMAD: Objection to form.

Q. Isn't that correct?

MR. HAMAD: He did not use those words. It's an unclear question.

MR. STEIN: Okay. You can state your objection. If the doctor finds it unclear, then he can tell me.

MR. HAMAD: Fair enough. I did.

A. The report there are two said okay for transfer, eight and the tenth.

Q. Okay. Do you have an opinion as to why he did not say that the others were okay for transfer?

A. It's likely from the test that he has from CF10, no division for A and no division for ten and they got results from both mutations.

Q. And what was it about that, the others, to cause him not to indicate that they were okay for transfer?

MR. HAMAD: Objection to form.

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MR. STEIN: Okay.

Q. Do you have an opinion as to why he did not label any of the others okay for transfer?

A. It looks like because of no amplification.

Q. What's the significance of there being no amplification?

A. No amplification means there is no information from that particular mutation.

Q. Okay. And so, therefore, those embryos which were numbered other than 8 and 10 would not be deemed okay for transfer. Is that correct?

MR. HAMAD: Objection to form.

That's totally misstating his testimony, but he can answer.

MR. STEIN: Okay.

A. The transfer of an embryo is finally determined by the patient, the couple, and physicians, because we -- again, I use my experience.

I think we had a case many years ago a patient wanted to transfer back, trisomy 21, which could lead to Down's syndrome and the physicians had to -- had a really difficult time to discuss. In the end it didn't transfer. I think a patient is the one that finally determines it, so I think a recommendation is here, but a transfer is determined by patient and the physicians.

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Q. Well, when the patient makes a decision as to whether to transfer an embryo on this list that is not recommended as okay for transfer in the report of the laboratory as was here, what factors should the patient take into consideration in making that decision?

MR. HAMAD: Objection to form.

Clearly beyond the scope of this witness' --

MR. STEIN: Okay.

MR. HAMAD: -- expertise.

A. Well, I think it involve in the transfer. I am not involved in it.

Q. Okay. If the patient -- if 8 and 10 were not transferred, then say as in this case, 7 was transferred during invitro fertilization, was there a higher risk of misdiagnosis with No. 7 than there was with either 8 or 10?

A. I don't see that a particular higher risk. There is a risk -- you know -- ADO is a risk for any embryos, even clearly you will get both results and still have the risk of ADO.

Q. Okay. What is it in the laboratory analysis that makes 8 and 10 okay for transfer and 7 not indicated by Dr. Hughes to be okay for transfer?

MR. HAMAD: Objection.

That was exactly my point.

MR. STEIN: You have made -- you got an objection, just state it. Object and let's move on.

MR. HAMAD: Mischaracterizing his prior testimony.

MR. STEIN: All right. Fine.

A. Well, I think the report indicates what they have from the test and on the column, the last column on the right is the one, the recommendation, call it here, they put. I think the one no amplification they didn't have the results and they have to 8 and 10, they have the results and recommend it.

That's what I can see from the report.

Q. So, in fact, 7 has -- if they don't have amplification of the CF10 allele, then there is a greater risk that the embryo being transferred would be at risk of having an affected baby?

MR. HAMAD: Objection to form.

Q. Isn't that so?

MR. LEUCHTMAN: Argumentative.

MR. HAMAD: It was already asked and he answered it.

He can answer it again.

A. Well, there is one -- well, to whole PGD is trying to reduce the risk.

Q. Right.

A. When you have one allele, CF11, which is G542X mutation in the test that indicates it is a normal one. At least we get some information there and that information will reduce the risk, so, I think, in the PGD whenever you have, you got the results is reduce the risk, so the risk for No. 7 compared to without doing it is reduced.

Q. Okay. Reduced from 25 percent to what?

A. To -- well, the one that it doesn't have amplification, then it's 50. So 25 percent, because the one that you already have -- well, that means if there is no ADO, then it's normal, right for that particular mutation on that side is normal. Well, of course, you have to think about the ADO occurs. It could happen with whatever percentage we are discussing now whether its 70 percent or what we quote five to ten percent, so that's the risk.

Q. You quote five to ten percent?

A. Of each mutation of one single mutation as ADO.

Q. Right. And then the risk of misdiagnosis would be five to ten percent in your view when you don't have the amplification?

A. Well, the risk of ADO for that mutation and then you have 50 percent that are unknown, those both events occurs, so you have 50 percent times the five to ten percent.

MR. HAMAD: What's that number?

Q. Which comes out to what?

A. Which comes out -- it should be 2.5 to five percent.

MR. HAMAD: That's for No. 7 we are talking about?

MR. LEUCHTMAN: Yes.

Q. 50 percent to 2.5 to five percent?

A. For ADO for X on 11 or G542. X is five to ten percent of ADO, because you already pick it up a normal allele, and you didn't see the T, which is five to ten percent. Exon ten, or delta F508, you didn't have information, so which means you have 50/50, right, so two events can happen, which the probability, then it's 50 times five or ten or five to ten.

Q. 50 times five to ten comes out to what?

A. Percent. Of a percent. Five to ten is allele drop out.

Now, on exon ten you don't have, you don't need to know allele drop out anymore, because you don't have it. If there is information there it is normal or it is affected, then you still have -- you have to calculate the ADO of that particular allele.

Q. It could be affected. It could be 100 percent?

MR. HAMAD: No.

A. That's why 50/50. It's a 50/50, because you don't know the information. You don't have the information.

Q. All right.

A. It's a 50/50.

Q. And so 50/50 on one side and five to ten percent on the other side?

A. On the other side.

Q. So it's greater -- if you have one side as 50/50, it's got to be greater than five to ten as the entire embryo, isn't it?

MR. HAMAD: Objection to form.

That's totally taking -- discounting the science. You have to have both together in order to fit the baby, you have to multiply it. That's what he has been doing.

Q. When you multiply 50/50 on one side and five to ten on the other, don't you have a greater number than five to ten for the combined risk of both of them together?

MR. HAMAD: These are percentage points that you are talking about?

MR. STEIN: Yes.

MR. HAMAD: 50 percent times five to ten

EXHIBIT 17

PROGRAM FOR IN-VITRO FERTILIZATION
REPRODUCTIVE SURGERY AND INFERTILITY

IVF / Andrology Laboratory
660 First Avenue, 5th Floor
New York, NY 10016

Tel: (212) 263-8990
Fax: (212) 263-0059

IVF SEMEN COLLECTION RECORD

Physician: Licciardi

Accession ID: 040738

Patient Name (Male Partner): Menachem Mendel Grossbaum Date of birth:

(Female Partner): Chaya R Grossbaum

How was this sample obtained:

Masturbation	
Intercourse with a condom	X
Intercourse with withdrawal	

How many days did you abstain before ejaculation? 2

The date 7/14/04 and time 7:45 AM / PM this sample was collected.

Were there any collection or transport problems (e.g., incomplete specimen, exposure to temperature extremes, or spilled sample)? YES or (NO)

If yes, please describe:

Are you taking any medication? YES or (NO). If yes, please indicate the name:

Have you had any illness in the past month? YES or (NO)

If yes, please specify:

STATEMENT OF VERIFICATION: I Menachem Grossbaum, verify that this sample was produced by me / my partner. The sample was given to a laboratory technologist whose signature appears below.

Signature of Patient — Date 7/14/04

The staff of NYU-PIVF is authorized to release the results of all testing performed on this semen specimen to my partner/spouse Chaya R Grossbaum for a period of one (1) year from the date of this authorization.

Signature — 7/14/04

OFFICE USE ONLY:

Type of specimen container:

Sterile 4.5 oz Specimen Container	X
Male Pak Sterile Condom	
Other Container	

Specimen collected at: Home or outside NYUMC-IVF facility ✓ **NYUMC-IVF facility**

Time Specimen was received: 9:10 **AM / PM**

EM — Laboratory Technologist — Date 7/14/04

EXHIBIT 18

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CASE NO. 07-CV-1359 (HAA)

CHAYA GROSSBAUM and MENACHEM GROSSBAUM, her spouse, individually and as guardians ad litem of the infant ROSIE GROSSBAUM,

Plaintiffs,

vs.

GENESIS GENETICS INSTITUTE, LLC, of the State of Michigan, MARK R. HUGHES, NEW YORK UNIVERSITY SCHOOL OF MEDICINE and NEW YORK UNIVERSITY HOSPITAL CENTER, both corporations in the State of New York, ABC CORPS, 1-10, and JOHN DOES 1-10

Defendants.

DEPOSITION UPON ORAL EXAMINATION OF:
MARK R. HUGHES, M.D.

TRANSCRIPT of the deposition of the witness, called for Oral Examination in the above-captioned matter, said deposition being taken pursuant to Notice, taken by and before KATHLEEN HAGEN, a Notary Public and Certified Shorthand Reporter of the State of New Jersey, at the law offices of NUSBAUM, STEIN, GOLDSTEIN, BRONSTEIN & KRON, P.A., 20 Commerce Boulevard, Succasunna, New Jersey, on Thursday, February 19, 2009, commencing at 10:30 a.m.

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M-A-R-K R. H-U-G-H-E-S, M.D., Ph.D., having offices at Genesis Genetics Institute, LLC, 5555 Conner Avenue, A22064, Detroit, Michigan, 48213, called as a witness, having been duly sworn, was examined and testified as follows:

DIRECT EXAMINATION BY MR. STEIN:

Q Dr. Hughes, as you know, we're here to take your deposition. I take it that you have previously submitted to a deposition?

A Yes.

Q About how many occasions?

A Twice.

Q Well, before I ask you about those, permit me to give you some guidelines and instructions, which we should operate under during this question and answer session. First, I should tell you that my questions and your answers are being recorded by the lady who sits to my right and your left, who is a Certified Shorthand Reporter, and if this case goes to trial, what you say here may be used at trial, so you should treat this question and answer session with the same onus as if you were giving testimony in open court, even though we're here in the law office. Do you understand that?

A Um-hum, I do.

Direct - Mark R. Hughes, M.D., Ph.D. Page 25

notice is there's only four letters in the genetic alphabet, not 26, and those four letters are "A", "T", "G" and "C" representing the four biochemicals of life, and the way in which they're strung together just like letters are strung together in a book will tell that cell what to do in "B", because it's the blueprint of information, it's the instruction set for that cell, and if you were to sit at your computer word processor and start typing the "A", "T", "G" and "C's", in that little cell using 10 pitch font, when you got finished, you would have a 300 volume set of the Encyclopedia Britanica worth of information, and then I tell them, in fact, that metaphor is not so crazy, because chromosomes are like the books of this gigantic encyclopedia of life, we have a certain number of these chromosome books, actually, we have two copies of most everyone, because we got one from our Mom and one from our Dad. And you can think of genes like paragraphs inside those chromosome books, and we have thousands and thousands of these gene paragraphs, each one of them saying something unique to the story of who we are, just like a paragraph in a book says something unique to that story, genes have a defined beginning, like a paragraph, you don't call it an indentation, we call it a "promotor", but it's the same idea, they have

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a defined end, they have a certain number of letters inside and sentences, so to speak, we call them "axons", and of those three thousand million letters, the two of you have a typographical error of a single letter in a single word in a single sentence in that paragraph in those three thousand million letters, and we have to study the smallest unit of life, one cell, for the smallest unit of inheritance, one gene for the smallest possible part of a gene, one single letter or, in your case, two different mutation changes, we have to be able to do that simultaneously, and we have to be able to do that overnight, and that pushes medical diagnostic technology to its absolute limit, its practical limit and its theoretical limit, because even in 100 years from now, it can't get smaller than testing one molecule, that's the smallest unit of biology, so we're at the limits of medical testing, and that's the reason why every hospital in the New York City area or the Boston area or the LA area send their samples to one of three laboratories in the whole United States.

Q One in Detroit, one in Chicago?

A And one in New Jersey.

Q In Livingston, New Jersey?

A Yeah. And so those, I take them down on the

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left in the box is they have 8, I then tell them it's not likely that all 8 of those are going to be perfect embryos, in fact, it's likely that they're not, for most couples, a couple of them won't grow, so don't expect that all of the 8 that they biopsy are going to be high quality embryos, because they almost never are, but the clinic is going to do the right thing, they're going to biopsy a cell from every embryo, even if they're shaking their head, saying that one's never going to make a baby, probably, you never know, so you want to give it the benefit of the doubt, so they biopsy a cell from each one, and they send it to us. Of course, we test every one, although, if the cell is having problems, and egg is having problems, the DNA inside is probably degrading, and oftentimes gives poor data or no data, and so, if we had a perfect result, we would have 8 embryos each with about 8 cells, 2 of them would be predicted to have two copies of the mutation MM, four of them would be predicted to be carriers like Mom and Dad, and two of them would be predicted to have gotten the normal gene from both of you, so statistically, because this is a 1 in 4 risk, if you have 8, two of them would be predicted statistically anyway to be affected, and 6 of them would be predicted to be healthy, and then I tell them I have this.

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Q And in number 2, 2 and 4 is strictly communicating the statistical --

A Yes.

Q -- information regarding the general population, is that correct?

A That's right.

Q Okay.

A So I tell them, Look, you might not make 2 and 6, you may not make any that have your disease or you might make 2 and 6 or 3 and 5 or 4 and 4 or 1 and 7 or 7 and 1, and we can't change it, and neither can you, but we'll test and see what we get, and hopefully we do see a risk of those 2 and 6, and in the process of that, I'm drawing the pictures, I'm putting down these numbers, and I have key lines that I always say, and I underline those at the same time.

Q Now, and this is -- and you're doing this as you're talking to the people, of course?

A Yes, I have a headset on.

Q And this is a form that has been prepared by you at Genesis Genetics, is that correct?

A Yes.

Q Now, I notice in one of the statements that you made, that you say, "Alternative treatments.." -- you say, quote, "..do not need

pre-implantation genetic diagnosis, and you can get pregnant and assume the risks that are inherent to the disease." You tell them that, is that right?
A Yes.
Q Now, you also seem to indicate that -- numerous times throughout your communication with the people, you suggest the requirement that they undergo amniocentesis or CV testing to confirm the information provided through PGD testing, is that correct?
A That's correct.
Q What -- if people are going to undergo amniocentesis or CV testing to protect themselves against having to endure the birth of a CF baby, what would be the reason for them to undergo the expense and inconvenience of PGD testing?
A To dramatically lower their risk. These couples will tell you, especially if they already have a child with the disease, that they are coming in saying, We know our risks are 25 percent, and we take this personally, we gave this to our baby, we don't want it to happen again, and 1 in 4 is pretty high odds, and so we want those risks reduced.
Q Well, they're still protected against having the baby if they do amniocentesis or CV testing, aren't they?

A They are, but they've got 15 weeks of incredibly high anxiety while they're waiting to have the procedure, and then, after you do an amniocentesis or a CVS, the sample for which you have hundreds of thousands of cells is taken to a laboratory and cultured for another week, and then it's tested in the laboratory, over the course of another week, so all of a sudden, they're at 16, sometimes 17, sometimes longer weeks waiting for the results of their pregnancy, and nobody wants to go through that, if they can help it, so by starting their pregnancy knowing that their risks are dramatically reduced, it makes it all that much more tenable; these couples will tell you that the risk is so high, that they're afraid to even have sex, oftentimes, because the risks are high. Not all patients say that, but many do, and so they come to this pretty amazing hoop jumping to build a family, and they don't need this, they go through it to lower their risks, not to zero, but a lot.
Q Well, in connection with your experience, to what number do they lower it?
A Less than 2 percent, significantly less than 2 percent, but it depends on the disease.
Q Well, we're talking here today only about CF.

A Well, if we've had four errors in 1000 cases, it's significantly less than 1 percent.
Q And you figure you tell the people that?
A Yeah, we'll tell them -- the field of PGD quotes a risk of 3 to 5 percent error for this kind of testing, and for chromosome testing, it's even higher, and now as we are learning about the amazing discrepancies of cells inside of an embryo, we're learning that there's all sorts of reasons why a cell that you biopsy might not represent the whole embryo, so the field across the world quotes risks in 3, 4, 5 percent. In our personal program, it's less than 2, actually less than 1.
Q Okay. Do you have a reason as to why your program experiences, as you indicated, even less than 1 percent in the field and the field is quoting 3 to 5?
A Well, we do more of this than any other laboratory in the world, we've been doing it longer than any other laboratory in the world, so I think experience has something to do with it, but we know that in each family, so none of these tests are off the shelf, every one of them are custom designed for the unique DNA of each couple, because your DNA is unique on the planet, and the DNA that you and your partner mix together to make a baby is unique, and every time

you do it, it's different and unique, and so the test that we make for you is designed specifically for you, so to tell somebody that a particular test has been done so many thousands of times and the liability is such and such, is true to a point of all of the PGD that's been done, but we tell them that your test will never have been used before on embryos that the two of you have made, for the mutations that you have, and it's not likely that it will ever be used again.
Q Well, even though the test may be unique to the individual DNA of a particular couple, is the formula by which you approach and design the test the same?
A The formula for the mutations that the couple has starts out the same, and then it's modified, based on their DNA sequences.
Q Okay.
A So we spend some weeks optimizing their test, prior to the case, to be sure that it will work.
Q When you, as you indicate, spend weeks prior to the test, I take it, designing the test that's going to work with this family, is that what you're saying?
A Yes.
Q And what do you -- I take it that you

don't have their particular DNA?
A Yes, yes, we do.
Q You get the DNA weeks before?
A Oh, yes, sometimes months.
Q And that's based on the blood samples you're sent?
A Yes, or cheek swab samples now.
Q Good. Were they blood samples back in 2004?
A Yes.
Q And then you -- from the blood samples, you ascertain the nature and character of their DNA, and then you use the formulas to the point that you can, and then you apply a trial and error method to design a test for this particular couple, is that what you're saying?
A That's correct.
Q Now, in your page 2 of your pre-case phone review, you mention that you have written, if you follow with me in the third sentence down on the page, and I quote, "You do not need PGD; remember, you can just get pregnant and have a prenatal test like CV or amnio, there are great OB's that do it in New York who could do this for you."
A The docs, d-o-c-s, doctors.

Q Do you recall telling that to the Grossbaums?
A I don't personally recall saying it, but I'm sure I did.
Q Okay. And did you inquire of them, at that time, whether they had any problem with amnio or CVS?
A There was no indication at any time that they had a problem with CVS or amniocentesis, because if they had said they wouldn't do that, I wouldn't have taken their case, and NYU knows that, and so do all the programs, we -- we must -- we must be monitoring the integrity of this complicated technology more frequently than every 9 months. If a couple says to me, How reliable is what you're doing? And I say, Well, pretty good, but we haven't looked for 9 months, that's not very reassuring, so from the beginning of this research project, we have always required that a follow-up prenatal test be performed, and if the patient doesn't want to do that, that's fine, because we can't take care of them.
Q Well, I'm sure, in the course of your experience, people have told you that -- well, withdraw that.
The purpose of doing a CVS or amnio is to

facilitate aborting a CF baby, is that true?
A No.
MR. HAMAD: Objection to form.
Q Well, what would be the purpose of doing an amnio and CVS test?
A To find out the integrity of the single cell testing that we're doing on this project. As a scientist, we have to be monitoring this. If we didn't, we would be -- it would be not scientific, and it would certainly be unethical.
Q So from your point of view, doing the CVS testing or the amnio testing of the fetus is purely for the scientific confirmation of the validity of your PGD test?
MR. HAMAD: Objection. Mischaracterizing the prior testimony.
Q Do you understand the question?
A There are many reasons to having a prenatal test. It's state of the art medical care of obstetrics, and we want to monitor the quality of our data, knowing that it isn't perfect. And we need to monitor it frequently, and the most frequent we can do it is at a CVS or an amniocentesis stage, so that's when we require the testing to be done. What you do with the information from an amnio or CVS is completely

up to you, of course, but the test itself has to be performed, we have it in our informed consents, we talk about it -- we mention it, and I got no indication I would have written it down, and I would not have taken this case.
Q There are from -- aside from the scientific need for PGD testing validation, the people involved would see the rationale for that, to determine whether they want to continue to give birth to a CV -- to a cystic fibrosis baby, wouldn't that be your expectation?
MR. LEUCHTMAN: I object to the form of the question.
MR. HAMAD: I join in that objection.
MR. LEUCHTMAN: Vague, ambiguous, and speculative.
MR. HAMAD: I join in that objection.
Q Do you understand the question?
A Please repeat it.
MR. LEUCHTMAN: Better yet, rephrase it.
Q When you say you require this testing by the CV and amnio testing by the mother of the fetus, do you have a discussion that the purpose of your requirement is for -- solely for PGD testing validation?

MR. LEUCHTMAN: Wait, wait, wait. Before you answer it, I'm going to object to the form of question, mischaracterizing previous testimony. I don't think he has said that integrity of test results is the sole purpose of amnio or CVS. He has said, in fact, although he hasn't been interrogated about what the other factors are, that it's multi-factorial, that there are a number of reasons why he does it or has that requirement, so the sole aspect of that question mischaracterizes the testimony.
Q Well, let me ask you this. What are the other reasons that you require amnio and CV testing, besides scientific validation of PGD testing?
MR. HAMAD: Objection. I think he also gave another reason, besides scientific validation of testing.
Q I'm asking, what are they?
A From my personal perspective of this project, that's the only reason, but a clinician might have an instruction with the patient about other reasons why this might be a good idea, as a chromosome abnormality, because of all kinds of other things that you can find with those sorts of tests, you can have the right doctors present at the time of delivery, if there's a

problem that you can head off at the pass, but from a laboratory perspective, our requirement is in order to monitor the data and it's a prerequisite of enrolling in the program.
Q Is there any form that you provide the family, in which they sign to agree to do this as a condition of your doing the testing?
MR. LEUCHTMAN: Do what, undergo amnio or CVS?
Q Right.
A Well, we talk about the fact that it's necessary, and there's an informed written consent that has it in there, and they sign the consent, and most patients don't ever bring it up as an issue, so it's just mentioned that you have to have it, and I'm assuming they're being honest and not deceptive. I mean, I'm halfway across the country talking to a patient that I wouldn't have to talk to, we go the extra mile in our laboratory to try to make sure that everything is on queue, and if a couple is going to be deceptive and dishonest with me, or dishonest, I don't know which, it's not my position to know, we just simply are very polite, but we tell them, I'm sorry, we can't take care of you.
Q Overall, aside from the limitation of CF

mutations in your -- in the entire spectrum of your testing, how many cases have you had where there was a misdiagnosis through PGD testing?
A There's -- we're not sure about one, so they're either 12 or 13 over the course of 15 years. We thought there was 14, but it turns out we could prove a couple got pregnant on their own, so it didn't count, so it was an error or at least it looked like an error, but in DNA technology, we can do a DNA fingerprint on an embryo when we do the test so we know which embryo made the baby, and we know that the right one was put in, and we know that the baby that they've got wasn't any of the embryos that they had in the incubator, but that's happened in the last four or five years of technology development. Back in 2003-4, that wasn't available yet.
Q Turning to page 3, there is a line about two-thirds of the way down the page that starts, "Need to follow up with CV and amnio". Do you see that line?
A Um-hum.
Q There is a circle on that line that has some letters inside. Can you tell us what those letters are?
A That says "Evans".
Q What is that, a name?

A Yes, that's a doctor in New York City who is world renowned at CFS and amnios, who has the lowest what -- well, he's as good as it gets, and I don't remember why I put that in there, but probably, I was going to recommend, once they're pregnant, that they go see him, but I don't know why, he's the person I would want them to see. I send other families to them, as well, but in a place like NYU, they have their own internal groups, and so that's probably why I have the question mark, because they'll take care of it for the family separate from me, but if they live in, you know, some little town in Montana, I need to get them to the right place, so I try to assist their genetic counselor in doing that.
Q Now, there's a page in your chart which lists what appears to be the sequencing category listing down with numbers 1 to 20 on the left-hand side. I'll show you the page I have reference to.
A Okay.
Q That looks to me a little bit like a diary of the various activities that your laboratory will undertake, from the point of view of initial inquiry until the baby is born, is that correct?
A Yeah, well, yeah, this has been a table that we've had for a long time, we have found it is

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Impossible to keep up with the outcomes, we have to beg the clinic to tell us if the patients even get pregnant. So the bottom part, we generally aren't filling out, unless they're going to donate embryos for research, then we have a part in there where we actually have their permission from the clinic to recontact the family, that's the bottom part.
Q Are there areas -- number 17, "post-case prenatal testing", and there appears to be a target, it has a date of 10/25/2005, with no completion date on there.
A Right.
Q Does that have any significance to you?
A Well, that was the date around which -- there's so many weeks difference between an amnio and a CVS, so the date is just picked as a time in between where a CV or an amniocentesis might be done in the pregnancy, and it's put there, so that's when the test would -- they should have the test, yeah, but we don't actually do the test, complete the test, and only under very rare occasions do we get the sample for the testing, that's when there isn't any other laboratory, commercial or academic, that could do the mutation test for the couple, so then we do the follow-up for ourselves for the mutation, but for something like cystic fibrosis,

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the sample would -- the test -- all of this becomes an obstetrical issue, it has nothing to do with us, other than we try to get the information back, obviously.
Q Have you had occasion where families tell you that they won't see the need to do amnio or CV, because they have religious aversion to aborting their fetus?
A Yes.
Q On how many occasions has that happened, in your experience?
A I don't know, probably 20 a year.
Q And those families are rejected for PGD testing?
A That's correct.
Q Do you have an occasion --
A Actually, there are other laboratories that might do it, and we tell them who those are, and they could contact them to find out if they have different guidelines.
Q Have they come out of NYU, as well as other referring institutions?
A I don't remember.
Q It appears, from your PGD analysis, that you analyzed 14 samples -- no, not quite.
A I recall 10, but let me look.

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Q Ten, I misspoke. I'll withdraw the question.
MR. LEUCHTMAN: What page are you referring to?
Q Well, it's -- there is a result statement, dated July 19, 2004, is that right?
A July 19, 2004, yeah.
Q Okay. You're looking at a form addressed to NYU Reproductive Center. That same chart happened to appear in an electronically signed chart, that was done by your company a few days prior, but the same information is on the chart. Now, you indicate, in the report, that you sequenced the father's mutation, is that correct?
A Um-hum, yes.
Q And I take it that, attached to your chart, is the record of the sequencing that appears, is that correct?
A Well, actually, his DNA and her DNA were tested weeks before this report, but then, it's also tested in parallel with their embryo samples on the same time.
Q Okay. Well, --
A As a control.
Q Well, in the chart we see -- I'm going to mark my copy, shall I say there are pages that appear

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to have graphs on them?
A Um-hum.
Q Okay. Do those graphs represent the sequencing?
A They would be, yeah.
Q Okay. And do they -- is the sequencing of the father's mutation in the graph?
A Yes.
Q Okay. And could you tell me where the sequencing of the father's mutation is in the graph?
A Well, no, this is -- let's see, this is his axon 11, so it's normal, so it shows his normal "G".
Q What page is that?
A This one, this is him, this is the father, that's his bar code, and this is his normal letter "G" in axon 11.
MR. STEIN: Okay, let me just mark it. I'll make the entire chart P- -- why don't we mark the original of the doctor's chart, so we'll have it, or rather still, we'll mark mine, and then we'll make copies of those that are marked. Let's mark the page on which the father's sequencing appears.
MR. HAMAD: Can you tell me what the number on the box here on the top is for that

page?
THE WITNESS: I'm sorry.
MR. LEUCHTMAN: What's the number?
THE WITNESS: Well, I don't know, these pages aren't numbered.
MR. HAMAD: Off the record.
(Discussion off the record.)
A This is MG PAT.
Q MG?
A Yeah, this is Morganstein-Grossbaum Paternal.
Q And which one is it?
A What's the question? So this is the father.
Q MG PAT?
A For paternal, P-A-T stands for paternal, M-A-T stands for maternal.
MR. LEUCHTMAN: There are two pages that have "MG PAT" at the top.
THE WITNESS: Yes, we do them twice, we double test everything, so we have two copies of the sequence of everyone.
Q Now, prior in the chart, to finding a page that says MG PAT, we have two pages marked "CG MAT"?
A Uh-huh.
Q And her name is Chaya Grossbaum, so "CG", I take it, is the mother?

A Uh-huh.
Q And prior to that, we have "BUFR-BOA" and "K".
A That's "control buffer blank".
Q Then, prior to that, we have "no indication". What does that mean?
A No indication.
Q I don't have that kind of a stamp, I have something called with "2643-15".
A Yeah, so that's the family number, and it's sample 15, so what happens is that the samples -- let me take you through this series. So the samples come from NYU, they're numbered, we take a photograph of that, so we know exactly what we received, each tube receives a bar code, they're locked into a cassette, this is how the cassette looks with the bar codes for the samples, in the order that they're run.
Q Okay.
A And then, this is the analysis, and so this is the family number. 15 would be sample 15.
Q Okay. So we see the sequencing numbers, and they have the numbers of each one of the tubes as 2, 3, right up to 15, is that right?
A That would be right, um-hum.
Q And what -- and do those numbers represent

the sequencing of the mutation in all of those tubes for both parents?
A This -- so these pictures are the sequencing of one of the two gene mutations in the family.
Q Okay.
A In this case, these numbers are for the 542X, axon 11.
Q That's the mother?
A Yes.
Q Okay. So that means that each one of the tubes were sequenced for the mother, is that right?
A Sequenced for the mother's -- the possibility of the mother's mutation, yes.
Q Okay. Now, and that's for all ten of the tubes, right?
A That would be right.
Q Okay. Now, you have sequencing for all ten of the father's --
A Sure.
Q -- mutation?
A Um-hum.
Q And where do I count those numbers, that would be axon 11?
A That would be axon 10, they're not in here. I don't have a copy of it. We have them, I just don't

have a copy of it. Xeroxing my set must be incomplete, these are taken off of machines, when you ask for the data, so, no, you don't have it, either, no, they're not in the Xerox set. The whole axon 10, the section is missing. We have to get those for you. You don't have them, either.
Q That's true.
A So the original set when it got Xeroxed, those pages are missing. I just have to get them.
Q Doctor, is it your testimony that the sequencing of the father's mutation exists, but it's just not been included in the materials that are in your possession today or have been provided to us in the past, is that correct?
A Absolutely.
Q Now, other than the initial telephone conversation that we've discussed, at the outset of your relationship with the amnio to be interpreted, is there any communication directly with the patient by your laboratory?
A Yes, there was an e-mail I didn't know about, but I found it when we were getting the records together.
Q And what was the content of the e-mail -- can you tell us first what the date of it was?

EXHIBIT 19

NEW YORK UNIVERSITY SCHOOL OF MEDICINE

Program for IVF,
Reproductive Surgery
and Infertility

660 First Avenue CAR 500
New York, NY 10016-3295
Telephone: (212) 263-8990
Facsimile: (212) 263-8827
www.nyuivf.com

Addendum to IVF/ET Transfer Consent – Embryo Biopsy and Preimplantation Genetic Diagnosis (PGD)

I Chaya R. Grossbaum- Morgenstern and my partner Menachem M. Grossbaum are known to be carriers for a genetic disorder:

____ X Chromosome-linked disorder ____ Recurrent aneuploidy ____ Chromosome translocation

✓ Single gene disorder Cystic Fibrosis

(e.g. Marfan's syndrome, Cystic fibrosis, Tay-Sachs, Fanconi's anemia, Von Hipple Landau syndrome, Epidermolysis bullosa)
(Please initial the specific genetic disorder that you carry.)

Because we do not wish to have any future children affected with a genetic disorder, we request that the embryos generated during our In Vitro Fertilization (IVF) cycle be biopsied and analyzed for the genetic disorder cited above. We understand that this procedure, preimplantation genetic diagnosis (PGD), can detect numerous genetic disorders in the embryo before it is transferred to the uterus and, when successful, allows for the possibility of pre-selecting "normal" embryos for conception, thus reducing the chance of giving birth to a child afflicted with a hereditary disease. We have been referred for PGD to the Program for In Vitro Fertilization, Reproductive Surgery and Infertility (PIVF) at the NYU School of Medicine where the IVF and biopsy procedures will be performed under the supervision of Dr. James A. Grifo M.D., Ph.D.. Genetic diagnosis of the cells, or blastomeres, removed from the embryos will be performed either at St. Barnabas Medical Center, West Orange, NJ or at the Center for Molecular Medicine and Genetics at Wayne State University, Detroit, MI.

We understand that the following steps are required:

1. Whenever appropriate, blood from each of us (approximately 10 milliliters) will be tested to verify that the diagnostic methods can detect the particular genetic disorder that we carry. This is particularly important whenever our samples are to be sent to the Center for Molecular Medicine and Genetics for analysis.

2. We will undergo an IVF treatment cycle at the Program for In Vitro Fertilization, Reproductive Surgery and Infertility in order to generate embryos for biopsy and analysis. We have signed the "In Vitro fertilization / Embryo Transfer ('IVF-ET') Program Consent Form – Options for 'Intracellular Sperm Injection' and 'Assisted Hatching' "of the Program for IVF (PIVF) which details the procedures and risks associated with the IVF procedure. We understand that we might require intracellular sperm injection (ICSI), the microsurgical injection of a single sperm using micromanipulators under an inverted microscope to fertilize the eggs, and have agreed to this option and have read the risks associated with ICSI as stated in the IVF consent form.

Initial: CRG-M MMG
Date: 6/04/04

3. On day 3 post egg retrieval each embryo containing 5 or more cells (blastomeres) will be subjected to a microsurgical biopsy in order to remove one or two cells. This procedure is also carried out using micromanipulators under a microscope . Should the female partner carry a chromosomal translocation a similar procedure will also be used to remove the first polar body of each egg prior to insemination. The biopsy procedure involves drilling a small hole through the zona pellucida of the embryo, a procedure which also "assists" with the hatching of the embryo as a blastocyst at a later stage of development. The cell(s) are gently removed from the embryo by suction. .

4. Genetic analysis of each polar body and/or blastomere will then be performed to determine its sex or if it carries our specific genetic disorder. Depending on our genetic disorder, we understand that the biopsied blastomeres will be analyzed using either fluoresence in situ hybridization (FISH, a procedure that enables us to count the numbers of certain chromosomes to check for sex, aneuploidy or translocations) or by molecular biology procedures designed to detect specific gene mutations. When FISH procedures are to be used, the blastomeres will be analyzed at St. Barnabas Medical Center, West Orange, NJ. When molecular biology procedures are to be used, the blastomeres will be analyzed at the Center for Molecular Medicine and Genetics at Wayne State University, Detroit, Michigan. We understand that will also be required to sign the appropriate consent form for these institutions. Genetic results will be available within 2 days following biopsy.

5. After the microsurgery, the embryos will be grown for one or two days after which time the "normal" embryos, i.e., those embryos with highly reduced possibilities of developing our specific genetic disorder – either unaffected embryos or, in cases where two mutations must be present to for the genetic disorder to appear, "carrier" embryos which carry only one mutation, will be transferred to uterus of the female partner should we decide in favor of such a transfer. We understand that it is possible that there may be no "normal" embryo available for transfer.

6. If there are "normal" embryos of suitable quality for future attempts to initiate a pregnancy using a frozen embryo transfer, these embryos may be cryopreserved with our permission. Details about cryopreservation are presented in the PIVF "Consent for cryopreservation of fertilized eggs/embryos" that we must also sign. ***Affected embryos carrying the genetic disorder or "normal" embryos displaying such poor development and morphology to be highly unlikely to initiate a pregnancy will be retested whenever possible and then discarded.***

7. Following embryo transfer, blood tests for human chorionic gonadotropin, a sign of pregnancy,will be conducted and once established, our pregnancy will be followed in a routine fashion. Fetal development will be carefully monitored by serial ultrasound studies. In addition, in order to confirm the genetic diagnosis, we agree that the female partner will undergo chorionic villus sampling or amniocentesis at the appropriate time, 10 weeks and 12-16 weeks respectively, and to inform PIVF of the outcome.

8. Finally, we understand that it is important for us to monitor the growth and development of our child(ren) carefully during the first 2 years of life with our pediatrician at his/her discretion.

We understand that the following risks may be associated with the PGD procedure :

1. We have been informed that the IVF procedure has a number of defined risks that happen very infrequently (less than 1%). These risks are detailed in the In Vitro Fertilization/Embryo Transfer ("IVF-ET") Program Consent Form -Options for "Intracellular Sperm Injection" and "Assisted Hatching" that you must also sign and include infection, bleeding, ovarian hyperstimulation syndrome, premature birth, ectopic pregnancy, miscarriage and failure to conceive. The risks associated with multiple pregnancies are also listed in the Program Consent Form for IVF.Multiple pregnancy, i.e., twin and triplet pregnancies, carry a significantly greater risk for prematurity and obstetrical and neonatal anomalies and occur at a

Initial: GRM-G MMG
Date: 1/10/04

frequency of about 30% in standard IVF. However, multiple pregnancy occurs less frequently with PGD because fewer embryos are generally transferred. We understand that preembryonic stage is an early stage of fertilized ovum development and occurs several days before implantation into the maternal uterus. At this early stage the embryo is relatively undifferentiated. Numerous animal studies and also human twin studies show that microsurgery of the oocyte and/or embryo, as described above, should not affect the normal development of the baby. However, since this procedure has been performed only in limited studies on human oocytes and embryos, its precise deleterious effects, if any, are unknown. In animal studies, there has been no apparent problem(s), and preliminary evidence with human embryos suggests that this will also be true. Therefore, because of the uncertainty of risks at present, it is not possible to describe the character and likelihood of the risks involved in microsurgery on the oocyte and/or embryo. The risks with IVF- embryo transfer procedures together with embryo microsurgery are also unknown but so far the clinical pregnancy rate for PGD at PIVF is greater than 30%. Although lower than the pregnancy rate for non-PGD IVF cycles, this is to be expected since with PGD only those embryos are transferred that will not develop the genetic disorder; genetically affected embryos capable of initiating a viable pregnancy must, nonetheless, be discarded.

2. We understand that because PGD is a new procedure, a major risk is that the procedure may not be successful. The genetic analysis may fail or be incorrect, although in PIVF's experience with 60+ patients to date, the accuracy has been greater than 90%. It is possible that a "normal" embryo may be incorrectly identified as "affected" and not transferred as a result. Conversely, we understand that an "affected" embryo may be incorrectly identified as "normal" leading to the possibility of an "affected" fetus and child. The other risks include genetic and developmental damage introduced during the procedure. However, we understand that, to detect such anomalies of the fetus, PIVF recommends that any PGD pregnancy be monitored very carefully by serial ultrasound examinations. In addition, requires that, at 10 weeks or 12-16 weeks respectively, chorionic villus sampling or amniocentesis (a collection of the fluid that surrounds the fetus) be performed to obtain for a comprehensive genetic analysis of amniotic fluid and cells. Finally, we understand that any abnormality of the fetus is identified or genetic disorders are detected by laboratory analysis, Dr. Grifo will discuss the implications of these findings with us in detail, and counsel us about our options.

We understand that, as patients undergoing preimplantation embryo testing, we must undergo an in vitro fertilization cycle and are not only responsible for the costs associated with this cycle but also PGD-related, supplemental costs. These costs include a PGD fee ($5000) that covers intracytoplasmic sperm injection and embryo biopsy. We understand that Dr. Marc Hughes will discuss with us the charges for the genetic diagnoses performed at Wayne State University; these charges (approximately $2000) include shipping costs for the biopsy specimens from PIVF to Michigan. We understand that the charges for FISH analysis at St. Barnabas Medical Center will range from $1500-$2500 depending on the analysis to be performed.

We understand that data from our IVF and PGD procedure must also be provided to the Centers for Disease Control and Prevention (CDC). The 1992 Fertility Clinic Success Rate and Certification Act requires that the CDC collect data on <u>all</u> assisted reproductive technology cycles performed in the United States annually and report success rates using these data. Because sensitive information will be collected on us, the CDC has applied for and received an "assurance of confidentiality" for this project under the provisions of the Public Health Service Act, Section 308 (d). This means that any information that the CDC has that identifies us will not be disclosed to anyone else without our consent. Thus, we understand that we cannot choose to have our information excluded and agree to provide PIVF with information regarding any future pregnancy, labor and delivery, and birth outcome resulting from the transfer of these cryopreserved embryos. We understand that it is important for us to remain in contact with PIVF; thus, we agree to advise PIVF promptly in writing of any change(s) in our mailing address or telephone number.

In summary, we understand that PGD will allow us to have a prenatal genetic diagnosis in hand prior to the establishment of pregnancy. This is a distinct advantage over the present methods, which would require us to

Initial: CRG-M mmg
Date: 6/04/04

wait until 9 to 16 weeks of pregnancy before determining if our fetus carries a genetic disorder. However, we understand that this PGD procedure is only specific for the particular genetic disorder that we have consulted Dr. Grifo for and not for all genetic disorders.

Chaya R Grossbaum-Mogenstern
Signature of Female Patient

Chaya R. Grossbaum-Mogenstern 6/04/04
Print Name and Date

Signature of Male Partner

menachem M Grossbaum
Print Name and Date

Signature of Witness

Kaycann Brown
Print Witness Name and Date

This consent form must be signed by both the patient and her partner in the presence of a member of the clinical or nursing staffs at PIVF or in the presence of a notary public.

I have consulted with and explained the contents of this consent form to the patient and her partner. All question(s) concerning the procedures have been answered.

Signature of Physician

Print Physician Name and Date

Initial: CRM-G MMG
Date: 6/04/04

EXHIBIT 20

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
DOCKET NO. 07-CV-359

CHAYA GROSSBAUM and MENCHEM GROSSBAUM, her spouse, individually, as Guardian ad Litem of the infant ROSIE GROSSBAUM,
Plaintiffs,

-against-

GENESIS GENETICS INSTITUTE, L.L.C., of the State of Michigan, MARK R. HUGHES, M.D., NEW YORK UNIVERSITY SCHOOL OF MEDICINE and NEW YORK UNIVERSITY HOSPITALS CENTER, both corporations in the State of New York, ABC CORPORATIONS 1-10 and JOHN DOE 1-10,
Defendants.

DEPOSITION of IMELDA WEILL, taken by the Plaintiffs at the offices of New York School of Medicine, 660 First Avenue, New York, New York, on Thursday, June 4, 2009, at 10:40 o'clock a.m., before Catherine M. Donahue, a Certified Court Reporter and Notary Public within and for the State of New York.

PHILIP A. FISHMAN COURT REPORTING
89 Headquarters Plaza
North Tower, 14th Floor
Morristown, New Jersey 07960
(973) 285-5331

A P P E A R A N C E S:

consent form is?

A. Yes.

Q. What do you tell them?

A. First of all, this is a legal document. We make sure that they read every word that was in there. If they don't understand it, they can always go back to their doctor to make sure. We try to tell them not to add anything on the consent like handwritten or pen, and if they are -- if they have no questions with it, they can sign it with the nurse. And if they have any questions, they can address the doctor and sign with the doctor.

Q. Do you stay in their presence while they read the form?

A. Not all the time, sir.

Q. And do the patients frequently tell you what the questions they have are when you witness the form?

MR. HAMAD: Objection to form. I don't understand the question.

You can answer if you do.

A. Again, we say if you have any questions after you have read it, you can refer to your doctor. They're always free to call anytime during the office hours. If there's no questions, then they just simply sign the consent. It would be witnessed by one of the

EXHIBIT 21

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
DOCKET NO. 07-CV-359

CHAYA GROSSBAUM and MENCHEM GROSSBAUM, her spouse, individually, as guardians ad litem of the infant, ROSIE GROSSBAUM, Plaintiffs, v. GENESIS GENETICS INSTITUTE, L.L.C., of the State of Michigan, MARK R. HUGHES, M.D., NEW YORK UNIVERSITY SCHOOL OF MEDICINE and NEW YORK UNIVERSITY HOSPITALS CENTER, both corporations in the State of New York, ABC CORPORATIONS 1-10 and JOHN DOE 1-10,	DEPOSITION OF: JAMES GRIFO

T R A N S C R I P T of the stenographic notes of the proceedings in the above-titled matter, as taken by PHILIP A. FISHMAN, a Certified Shorthand Reporter and Notary Public of the State of New Jersey, held at the offices of DR. JAMES GRIFO, 660 First Avenue, New York, New York, on Wednesday, June 24, 2009, commencing at 4:00 in the afternoon.

PHILIP A. FISHMAN
COURT REPORTING AGENCY
89 Headquarters Plaza North
14th Floor
Morristown, New Jersey 07960
(973)285-5331 - FAX (732)605-9391

A P P E A R A N C E S :

NUSSBAUM, STEIN, GOLDSTEIN, BRONSTEIN & KRON, ESQS.
BY: LEWIS STEIN, ESQ.
Appearing on behalf of the Plaintiffs

STEPHEN N. LEUCHTMAN, P.C.
BY: STEPHEN N. LEUCHTMAN, ESQ.
Appearing on behalf of the Defendant Genesis Genetics Institute, L.L.C., and Dr. Hughes

MARSHALL, DENNEHEY, WARNER, COLEMAN & GOGGIN, ESQS.
BY: JAMELE A. HAMAD, ESQ.
Appearing on behalf of the Defendants New York University School of Medicine and New York University Hospitals Center

* * *

Patients decide on their own whether or not they do amniocentesis or CVS. That's not our decision. It's our recommendations because of limitations of the test, because the accuracy is not 100 percent. We take their 25 percent risk and make it close to -- you know -- one to three percent to give them a better chance of having a healthy baby, but we don't give them 100 percent of having a healthy baby, and amnio and CVS have more accuracy and less diagnostic limitation than the PGD test.

Q. And if the patient declines and indicated at the time that they were going to undertake PGD testing that they would not do amnio or CVS testing, would that prevent you from going ahead with the implantation in the IVF work?

A. No. We advise patients, but they make their own decisions -- you know -- in the initial consult with a PGD patient, I always go over the fact these tests aren't 100 percent accurate and we recommend CVS or amnio, and if they say to me, "We are not doing CVS or amnio," we note it and treat them. We still give them an advantage of their 25 percent risk, and making it a lot lower number.

We have helped many patients have healthy babies, we would have had a much higher chance of having an

EXHIBIT 22

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NUSBAUM, STEIN, GOLDSTEIN,
BRONSTEIN & KRON, P.A.
20 Commerce Blvd., Suite E
Succasunna, NJ 07876
(973) 584-1400
Attorneys for Plaintiffs

CHAYA GROSSBAUM and MENACHEM GROSSBAUM, her spouse, individually and as guardians *ad litem* of the infant ROSIE GROSSBAUM,	DOCKET NO.:
Plaintiffs,	CIVIL ACTION
vs.	
GENESIS GENETICS INSTITUTE, LLC, of the State of Michigan, MARK R. HUGHES, NEW YORK UNIVERSITY SCHOOL OF MEDICINE and NEW YORK UNIVERSITY HOSPITALS CENTER, both corporations in the State of New York, ABC CORPS. 1-10, and JOHN DOES 1-10,	**COMPLAINT AND JURY DEMAND**
Defendants.	

Plaintiffs, Chaya Grossbaum and Menachem Grossbaum, her spouse, individually and as guardians *ad litem* of the infant Rosie Grossbaum, complaining of the Defendants, Genesis Genetics Institute, LLC, a limited liability corporation in the State of Michigan, New York University School of Medicine and New York University

Hospitals Center, both corporations in the State of New York, ABC Corps. 1-10, and John Does 1-10, allege and say:

JURISDICTION

1. The Plaintiffs, Chaya Grossbaum and Menachem Grossbaum, her spouse (hereafter "Plaintiffs"), are citizens of the State of New Jersey, residing at 122 Lake Valley Road, Morristown, New Jersey.

2. At all relevant times, Defendants, New York University School of Medicine and New York University Hospitals Center, were corporations of the State of New York situated at 540 First Avenue, New York, New York.

3. At all relevant times herein, Defendant Genesis Genetics Institute was a limited liability corporation in the State of Michigan with offices at 1380 East Jefferson Avenue, Detroit, Michigan, and the Defendant, Mark R. Hughes, a physician and resident of the State of Michigan, was its director.

4. Jurisdiction is proper within this United States District Court for the District of New Jersey, the venue within which the Plaintiffs presently reside, pursuant to 28 U.S.C. §1332 as there is diversity of citizenship among the parties and the amount in controversy exceeds $75,000.00, exclusive of costs, interest and punitive damages.

COUNT ONE

1. Plaintiffs repeat and make a part hereof the Jurisdictional paragraphs of this Complaint as if set forth fully at length herein.

2. Prior to March 2004, the Plaintiffs, in contemplation of parenthood, were tested for genetic mutations that would predispose any infant which they produced to disability and impairment. Said testing resulted in identifying both of the Plaintiffs,

Chaya Grossbaum and Menachem Grossbaum, as carriers of the cystic fibrosis gene mutation.

3. On or about March 30, 2004, the Plaintiff, Chaya Grossbaum, came under the care of the New York University School of Medicine, Department of Obstetrics and Gynecology, in their program for *in vitro* fertilization and pre-implantation genetic diagnosis.

4. The aforesaid physicians at Defendant, NYU School of Medicine, advised the Plaintiffs to undergo pre-implantation genetic diagnosis (PGD) of their embryos to eliminate the potentional for a cystic fibrosis baby, and were recommended for PGD studies to be undertaken by Defendant, Genesis Genetics Institute, LLC (hereinafter "Genesis Genetics"), and its director, Defendant, Dr. Mark R. Hughes, in Detroit Michigan.

5. Thereafter, the Plaintiffs consulted with Defendants, Genesis Genetics and Dr. Mark R. Hughes, and were advised that Genesis Genetics would be able to identify the presence of the cystic fibrosis gene mutations in the embryos pre-implantation so they would avoid parenting a baby with such disability.

6. On or about July 14, 2004, the Plaintiffs underwent retrieval and insemination procedures at Defendant, NYU Hospitals Center, for the creation of embryos that were forwarded to Defendant, Genesis Genetics, in Detroit, Michigan, for pre-implantation genetic diagnosis.

7. On or about July 19, 2004, the Defendant, Genesis Genetics, reported the results of their diagnostic studies to the physicians at Defendant, NYU School of Medicine, advising that 2 of 10 embryos were free of the genetic mutations that were

suitable for a cystic fibrosis free infant, and those were the embryos that were said to be implanted.

8. On March 25, 2005, the Plaintiffs gave birth to a baby girl, Infant Plaintiff Rosie Grossbaum, at Saint Clare's Hospital, Denville, New Jersey, who was disabled with cystic fibrosis.

9. On information and belief, the physicians of Defendants, NYU School of Medicine and NYU Hospitals Center, failed to meet the required standards of care in selecting and confirming the appropriate diagnostic tests that were performed by Defendant Genesis Genetics, and thereafter, implanted a defective embryo resulting in the birth of a cystic fibrosis infant.

10. As a further result of the negligence of the Defendants, NYU School of Medicine and NYU Hospitals Center, the Plaintiff Chaya Menachem has suffered and will continue to suffer considerable emotional distress with respect to the delivery and upbringing of the infant Plaintiff Rosie Grossbaum due to the special needs for care and treatment of a cystic fibrosis baby and the attendant risks to the child.

11. As a further result of the negligence of the Defendants, NYU School of Medicine and NYU Hospitals Center, the Plaintiffs will suffer considerable costs and expenses for the care and treatment of their cystic fibrosis baby, infant Plaintiff Rosie Grossbaum.

12. As a further result of the negligence of the Defendants, NYU School of Medicine and NYU Hospitals Center, the infant Plaintiff, Rosie Grossbaum, upon reaching the age of maturity, will be required to expend considerable sums of money in an effort to treat and manage her disabilities arising from cystic fibrosis.

WHEREFORE, the Plaintiffs, Chaya, Menachem, and infant Rosie Grossbaum, demand judgment against the Defendants, NYU School of Medicine and NYU Hospitals Center, for damages, interest, and cost of suit.

COUNT TWO

1. Plaintiffs repeat and make a part hereof the Jurisdictional and Count One paragraphs of this Complaint as if set forth fully at length herein.

2. At all times herein, the Defendant Genesis Genetics held itself as an expert in performing pre-implantation diagnosis of embryos that are at risk for the birth of a cystic fibrosis infant.

3. At the relevant times herein, the Defendants, Genesis Genetics and Mark R. Hughes, assured the Plaintiffs that they had nothing to worry about in connection with the process of pre-implantation diagnosis, and they could be assured of a cystic fibrosis free baby on subsequent *in vitro* fertilization.

4. The Defendant Genesis Genetics performed diagnostic procedures in such a manner as to depart from accepted standards of care resulting in the delivery of a cystic fibrosis baby, the infant Plaintiff Rosie Grossbaum, by the Plaintiffs, Chaya and Menachem Grossbaum.

5. As a further result of the negligence of the Defendants, Genesis Genetics and Mark R. Hughes, the Plaintiff Chaya Menachem has suffered and will continue to suffer considerable emotional distress with respect to the delivery and upbringing of the infant Plaintiff Rosie Grossbaum due to the special needs for care and treatment of a cystic fibrosis baby and the attendant risks to the child.

6. As a further result of the negligence of the Defendants, Genesis Genetics and Mark R. Hughes, the Plaintiffs will suffer considerable costs and expenses for the care and treatment of their cystic fibrosis baby, infant Plaintiff Rosie Grossbaum.

7. As a further result of the negligence of the Defendants, Genesis Genetics and Mark R. Hughes, the infant Plaintiff, Rosie Grossbaum, upon reaching the age of maturity, will be required to expend considerable sums of money in an effort to treat and manage her disabilities arising from cystic fibrosis.

WHEREFORE, the Plaintiffs, Chaya Grossbaum, Menachem Grossbaum, and infant Rosie Grossbaum, demand judgment against the Defendants, Genesis Genetics and Mark R. Hughes, for damages, interest, and cost of suit.

COUNT THREE

1. Plaintiffs repeat and make a part hereof the Jurisdictional and Counts One through Two paragraphs of this Complaint as if set forth fully at length herein.

2. Defendants ABC Corps. 1-10 are fictitious entities whose identities are currently unknown and who shall be impleaded as soon as they are identified.

3. Defendants ABC Corps. 1-10 are entities presently unknown who through further discovery may be identified as being negligently involved in either the pre-implantation diagnosis or the implantation of the cystic fibrosis carrying embryos that resulted in the delivery of the cystic fibrosis infant Plaintiff Rosie Grossbaum.

WHEREFORE, the Plaintiffs, Chaya, Menachem, and infant Rosie Grossbaum, demand judgment against the Defendants, ABC Corps. 1-10, Genesis Genetics, Mark R. Hughes, NYU School of Medicine and NYU Hospitals Center, John Does 1-10, for damages, interest, and cost of suit.

COUNT FOUR

1. Plaintiffs repeat and make a part hereof the Jurisdictional and Counts One through Three paragraphs of this Complaint as if set forth fully at length herein.

2. Defendants John Does 1-10 are fictitious individuals whose identities are currently unknown and who shall be impleaded as soon as they are identified.

3. Defendants John Does 1-10 are persons presently unknown who through further discovery may be identified as being negligently involved in either the pre-implantation diagnosis or the implantation of the cystic fibrosis carrying embryos that resulted in the delivery of the cystic fibrosis infant Plaintiff Rosie Grossbaum.

WHEREFORE, the Plaintiffs, Chaya, Menachem, and infant Rosie Grossbaum, demand judgment against the Defendants, John Does 1-10, Genesis Genetics, Mark R. Hughes, NYU School of Medicine and NYU Hospitals Center, ABC Corps. 1-10, for damages, interest, and cost of suit.

JURY DEMAND

Plaintiffs hereby demand a trial by jury as to all issues.

NUSBAUM, STEIN, GOLDSTEIN
BRONSTEIN & KRON, P.A.
Attorney for Plaintiffs

Dated: March 23, 2007

By: Lewis Stein /s/
Lewis Stein

JS 44 (Rev. 11/04)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

Chaya Grossbaum and Menachem Grossbaum, her spouse, individually and as guardians ad litem of the infant Rosie Grossbaum

(b) County of Residence of First Listed Plaintiff MORRIS
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)
973-584-1400
Lewis Stein, Esq., NUSBAUM, STEIN, ET AL.
20 Commerce Blvd., Succasunna, NJ 07876

DEFENDANTS

Genesis Genetics Institute, LLC, of the State of Michigan, Mark R. Hughes, NYU School of Medicine and NYU Hospitals Center, et al.

County of Residence of First Listed Defendant WAYNE
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated or Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated and Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
☐ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	☐ 610 Agriculture	☐ 422 Appeal 28 USC 158	☐ 400 State Reapportionment
☐ 120 Marine	☐ 310 Airplane	☒ 362 Personal Injury - Med. Malpractice	☐ 620 Other Food & Drug	☐ 423 Withdrawal 28 USC 157	☐ 410 Antitrust
☐ 130 Miller Act	☐ 315 Airplane Product Liability	☐ 365 Personal Injury - Product Liability	☐ 625 Drug Related Seizure of Property 21 USC 881	PROPERTY RIGHTS	☐ 430 Banks and Banking
☐ 140 Negotiable Instrument	☐ 320 Assault, Libel & Slander	☐ 368 Asbestos Personal Injury Product Liability	☐ 630 Liquor Laws	☐ 820 Copyrights	☐ 450 Commerce
☐ 150 Recovery of Overpayment & Enforcement of Judgment	☐ 330 Federal Employers' Liability	PERSONAL PROPERTY	☐ 640 R.R. & Truck	☐ 830 Patent	☐ 460 Deportation
☐ 151 Medicare Act	☐ 340 Marine	☐ 370 Other Fraud	☐ 650 Airline Regs.	☐ 840 Trademark	☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)	☐ 345 Marine Product Liability	☐ 371 Truth in Lending	☐ 660 Occupational Safety/Health	SOCIAL SECURITY	☐ 480 Consumer Credit
☐ 153 Recovery of Overpayment of Veteran's Benefits	☐ 350 Motor Vehicle	☐ 380 Other Personal Property Damage	☐ 690 Other	☐ 861 HIA (1395ff)	☐ 490 Cable/Sat TV
☐ 160 Stockholders' Suits	☐ 355 Motor Vehicle Product Liability	☐ 385 Property Damage Product Liability	LABOR	☐ 862 Black Lung (923)	☐ 810 Selective Service
☐ 190 Other Contract	☐ 360 Other Personal Injury		☐ 710 Fair Labor Standards Act	☐ 863 DIWC/DIWW (405(g))	☐ 850 Securities/Commodities/ Exchange
☐ 195 Contract Product Liability			☐ 720 Labor/Mgmt. Relations	☐ 864 SSID Title XVI	☐ 875 Customer Challenge 12 USC 3410
☐ 196 Franchise			☐ 730 Labor/Mgmt. Reporting & Disclosure Act	☐ 865 RSI (405(g))	☐ 890 Other Statutory Actions
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	☐ 740 Railway Labor Act	FEDERAL TAX SUITS	☐ 891 Agricultural Acts
☐ 210 Land Condemnation	☐ 441 Voting	☐ 510 Motions to Vacate Sentence	☐ 790 Other Labor Litigation	☐ 870 Taxes (U.S. Plaintiff or Defendant)	☐ 892 Economic Stabilization Act
☐ 220 Foreclosure	☐ 442 Employment	Habeas Corpus:	☐ 791 Empl. Ret. Inc. Security Act	☐ 871 IRS—Third Party 26 USC 7609	☐ 893 Environmental Matters
☐ 230 Rent Lease & Ejectment	☐ 443 Housing/ Accommodations	☐ 530 General			☐ 894 Energy Allocation Act
☐ 240 Torts to Land	☐ 444 Welfare	☐ 535 Death Penalty			☐ 895 Freedom of Information Act
☐ 245 Tort Product Liability	☐ 445 Amer. w/Disabilities - Employment	☐ 540 Mandamus & Other			☐ 900Appeal of Fee Determination Under Equal Access to Justice
☐ 290 All Other Real Property	☐ 446 Amer. w/Disabilities - Other	☐ 550 Civil Rights			☐ 950 Constitutionality of State Statutes
	☐ 440 Other Civil Rights	☐ 555 Prison Condition			

V. ORIGIN (Place an "X" in One Box Only)

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
Div.

Brief description of cause: Plaintiffs sue Defendants involved in providing pre-implant. genetic diagnosis which was faulty and resulted in cystic fibrosis baby.

VII. REQUESTED IN COMPLAINT: ☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23 DEMAND $ CHECK YES only if demanded in complaint: JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE DOCKET NUMBER

DATE: March 23, 2007

SIGNATURE OF ATTORNEY OF RECORD: Lewis Stein/s/

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

JS 44 (Rev. 11/04)

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(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)
973-584-1400
Lewis Stein, Esq., NUSBAUM, STEIN, ET AL.
20 Commerce Blvd., Succasunna, NJ 07876

DEFENDANTS

Genesis Genetics Institute, LLC, of the State of Michigan, Mark R. Hughes, NYU School of Medicine and NYU Hospitals Center, et al.

County of Residence of First Listed Defendant WAYNE
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

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- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated or Principal Place of Business in This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated and Principal Place of Business in Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

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☐ 190 Other Contract	☐ 360 Other Personal Injury		☐ 710 Fair Labor Standards Act	☐ 863 DIWC/DIWW (405(g))	☐ 850 Securities/Commodities/ Exchange
☐ 195 Contract Product Liability			☐ 720 Labor/Mgmt. Relations	☐ 864 SSID Title XVI	☐ 875 Customer Challenge 12 USC 3410
☐ 196 Franchise			☐ 730 Labor/Mgmt. Reporting & Disclosure Act	☐ 865 RSI (405(g))	☐ 890 Other Statutory Actions
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	☐ 740 Railway Labor Act	FEDERAL TAX SUITS	☐ 891 Agricultural Acts
☐ 210 Land Condemnation	☐ 441 Voting	☐ 510 Motions to Vacate Sentence	☐ 790 Other Labor Litigation	☐ 870 Taxes (U.S. Plaintiff or Defendant)	☐ 892 Economic Stabilization Act
☐ 220 Foreclosure	☐ 442 Employment	Habeas Corpus:	☐ 791 Empl. Ret. Inc. Security Act	☐ 871 IRS—Third Party 26 USC 7609	☐ 893 Environmental Matters
☐ 230 Rent Lease & Ejectment	☐ 443 Housing/ Accommodations	☐ 530 General			☐ 894 Energy Allocation Act
☐ 240 Torts to Land	☐ 444 Welfare	☐ 535 Death Penalty			☐ 895 Freedom of Information Act
☐ 245 Tort Product Liability	☐ 445 Amer. w/Disabilities - Employment	☐ 540 Mandamus & Other			☐ 900Appeal of Fee Determination Under Equal Access to Justice
☐ 290 All Other Real Property	☐ 446 Amer. w/Disabilities - Other	☐ 550 Civil Rights			☐ 950 Constitutionality of State Statutes
	☐ 440 Other Civil Rights	☐ 555 Prison Condition			

V. ORIGIN (Place an "X" in One Box Only)

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
Div.

Brief description of cause: Plaintiffs sue Defendants involved in providing pre-implant. genetic diagnosis which was faulty and resulted in cystic fibrosis baby.

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE DOCKET NUMBER

DATE
March 23, 2007

SIGNATURE OF ATTORNEY OF RECORD
Lewis Stein/s/

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

EXHIBIT 23

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

Mark R. Hughes, M.D.
In Propria Persona
1380 East Jefferson Avenue
Detroit, MI 48207
(313) 250-6900
In Propria Persona for Defendants GENESIS GENETICS INSTITUTE and MARK R. HUGHES, MD

STEPHEN N. LEUCHTMAN, P.C.
Stephen N. Leuchtman
23855 Northwestern Highway
Southfield, MI 48075
(248) 948-9696, Ext. 143
Attorneys for Defendants GENESIS GENETICS INSTITUTE, LLC and MARK R. HUGHES, MD

CHAYA GROSSBAUM and MENACHEM GROSSBAUM, her spouse, individually and as guardians *ad litem* of the infant ROSIE GROSSBAUM, Plaintiffs, vs. GENESIS GENETICS INSTITUTE, LLC, of the State of Michigan, MARK R. HUGHES, NEW YORK UNIVERSITY SCHOOL OF MEDICINE and NEW YORK UNIVERSITY HOSPITALS CENTER, both corporations in the State of New York, ABC CORPS. 1-10, and JOHN DOES 1-10, Defendants.	DOCKET NO. 07-CV-1359 (HAA) CIVIL ACTION **ANSWER ON BEHALF OF DEFENDANTS GENESIS GENETICS INSTITUTE, LLC and HUGHES, only**

Defendants, GENESIS GENETICS INSTITUTE, LLC and MARK R. HUGHES, M.D., answer Plaintiffs' Complaint as follows:

JURISDICTION

1. Neither admitted nor denied for lack of information and belief.

2. No answer required from these Defendants.

3. Admitted.

4. Neither admitted nor denied for lack of information and belief.

COUNT ONE

1. These Defendants hereby repeat their responses to the Jurisdictional paragraphs of Plaintiffs' Complaint as if set forth in full herein.

2. No answer required from these Defendants.

3. No answer required from these Defendants.

4. No answer required from these Defendants.

5. Denied in the form and manner alleged.

6. Admitted in so far as the allegation pertains to these Defendants.

7. Denied in the form and manner alleged.

8. Neither admitted nor denied for lack of information and belief.

9. No answer required from these Defendants.

10. No answer required from these Defendants.

11. No answer required from these Defendants.

12. No answer required from these Defendants.

No prayer for relief required from these Defendants.

COUNT TWO

1. These Defendants hereby repeat their responses to the Jurisdictional and Count One paragraphs of Plaintiffs' Complaint as if set forth in full herein.

2. Admitted.

3. Denied.

4. Denied.

5. Denied.

6. Denied.

7. Denied.

WHEREFORE, these Defendants pray for Judgment in their favor, together with costs and attorney fees.

COUNT THREE

1. These Defendants hereby repeat their responses to the Jurisdictional and Counts One and Two paragraphs of Plaintiffs' Complaint as if set forth in full herein.

2. No answer required from these Defendants.

3. No answer required from these Defendants.

WHEREFORE, these Defendants pray for Judgment in their favor, together with costs and attorney fees.

COUNT FOUR

1. These Defendants hereby repeat their responses to the Jurisdictional and Counts One through Three paragraphs of Plaintiffs' Complaint as if set forth in full herein.

2. No answer required from these Defendants.

3. No answer required from these Defendants.

WHEREFORE, these Defendants pray for Judgment in their favor, together with costs and attorney fees.

FIRST SEPARATE DEFENSE

Recovery is barred for some of the claims set forth in this action by reason of the expiration of the applicable Statute of Limitations.

SECOND SEPARATE DEFENSE

The injuries or damages sustained by plaintiffs were the result of conditions or actions of third persons over whom these defendants exercised no supervision or control.

CROSSCLAIM FOR CONTRIBUTION

These defendants demand contribution from all co-defendants named in the Complaint under the Joint Tortfeasors Contribution Act, as more fully set forth at N.J.S.A. 25A:53-1 et seq.

ANSWER TO CROSSCLAIMS

These defendants deny the allegations of any and all crossclaims filed or which may be filed against these defendants.

JURY DEMAND

These Defendants hereby demand a trial by jury as to all issues in this case.

PROVISIONAL DESIGNATION OF TRIAL COUNSEL

Please be advised that Stephen N. Leuchtman, Esq. is hereby provisionally designated as trial counsel on behalf of defendants Hughes and Genesis Genetics Institute, LLC pending and contingent upon his appointment as counsel pro hac vice.

REQUEST FOR ALLOCATION PURSUANT TO RULE 4:7-5 (c)

If any co-defendant settles prior to trial, these defendants will seek an allocation

of the percentage of negligence by the fact finder against the settling defendant or defendants. We will seek this allocation whether or not we have formally filed a cross-claim against the settling defendant or defendants. We will rely upon examination and cross-examination of the plaintiffs' expert witnesses and any and all other witnesses at the time of trial, in support of this allocation . You are being apprised of this pursuant to N.J. Court Rule 4:7-5(c) and Young v. Latta, 123 N.J. 584 (1991).

DEMAND FOR AFFIDAVIT OF MERIT

Please defendants hereby demand that the plaintiffs serve an Affidavit of Merit pursuant to N.J.S.A. 2A: 53a–27.

MARK R. HUGHES, M.D.

By: Mark R Hughes
Mark R. Hughes
1380 East Jefferson Avenue
Detroit, MI 48207
In Propria Persona for
MARK R. HUGHES, M.D. and
GENESIS GENETICS INSTITUTE, LLC.

STEPHEN N. LEUCHTMAN, P.C

By:
Stephen N. Leuchtman
23855 Northwestern Highway
Southfield, MI 48207
Attorney for MARK R. HUGHES, M.D. and GENESIS GENETICS INSTITUTE, LLC.

Dated: September 17, 2007

PROOF OF SERVICE
THE UNDERSIGNED STATES, UNDER PENALTY OF PERJURY, THAT ON SEPTEMBER 17, 2007, HE PLACED COPIES OF THE WITHIN DOCUMENT IN ENVELOPES ADDRESSED TO THE COURT AND OTHER COUNSEL IN THIS CAUSE AND CAUSED THE ENVELOPES TO BE PLACED IN THE APPROPRIATE RECEPTACLE OF THE UNITED STATES POSTAL SERVICE, WITH FIRST CLASS POSTAGE THEREON.

STEPHEN N. LEUCHTMAN

EXHIBIT 24

JOHNS HOPKINS
UNIVERSITY

Institute of Genetic Medicine
733 N. Broadway
BRB Suite 551/Room 559
Baltimore, MD 21205
PHONE: 410-955-1773/FAX: 410-614-0213
EMAIL: gcutting@jhmi.edu

Garry R. Cutting, MD
Professor, Pediatrics and Medicine
Aetna/U.S. Healthcare Professor of Medical Genetics

September 29, 2009

Mr. Lewis Stein
Nusbaum, Stein, Goldstein, Bronstein & Kron
Counsellors at Law
20 Commerce Boulevard
Succasunna, NJ 07876

RE: Grossbaum vs Genesis Genetics et al

Dear Mr. Stein,

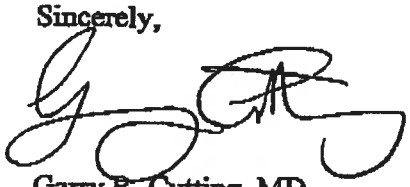
You have asked me to provide an opinion in the above referenced case. I have reviewed records that were provided by Genesis Genetics and New York University School of Medicine, as well as depositions of Dr. Mark Hughes, Dr. Licciardi and Alexis Adler, and publications regarding multiplex marker analysis provided by Dr. Rechitsky. As I understand, the Grossbaums underwent preimplantation genetic diagnosis in which egg retrieval, *in vitro* fertilization, and embryo biopsy performed at NYU IVF Clinic. Genetic diagnosis for cystic fibrosis was performed by Genesis Genetics on samples provided by NYU. The child that was born to the Grossbaums as a result of this procedure was found to be affected with cystic fibrosis.

I have formed the opinion that there are two areas where Genesis Genetics and the NYU IVF Clinic failed to offer a reasonable level of care. The first is in the counseling of the Grossbaums regarding alternatives for embryo transfer after it was discovered that the embryos recommended for transfer by Genesis Genetics were not suitable for transfer. Allele dropout (aka ADO) is a well established source of error in preimplantation genetic diagnosis. From the deposition of Dr. Licciardi, it was apparent that he was not aware of this potential cause for error. Dr. Licciardi indicated during his deposition that he did not understand the results of the genetic testing results transmitted by Genesis Genetics. There is also no documentation of what was said during the counseling session between Dr. Licciardi and the Grossbaums regarding the risks of potential sources of error. Thus, Dr. Licciardi failed to adequately appraise the Grossbaums of the potential risks of using alternative embryos for transfer.

The second area of concern relates to the diagnostics performed by Genesis Genetics. The use of additional markers encompassing a gene such as CFTR has been shown to reduce errors due to allele dropout. Numerous manuscripts had been published and abstracts presented at national and international meetings before the date of the Grossbaums' procedure indicating the value of including genetic markers to minimize errors due to ADO. Genesis Genetics is a high profile provider of PGD services and has by their report, performed many cases of PGD for cystic fibrosis. Thus, it is reasonable to expect that Genesis Genetics would have offered multiplex DNA markers to minimize the risk of error due to ADO in the Grossbaum case. If the laboratory was unable to offer this service, then the Grossbaums should have been informed so that they would have the option to select other services that offered PGD using multiplex markers.

Please contact me should you have any further questions regarding this case.

Sincerely,



Garry R. Cutting, MD
Professor, Pediatrics and Medicine
Director, Post-Doctoral Training Program
Director, DNA Diagnostic Laboratory

EXHIBIT 25

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November 12, 2009

Lewis Stein
Nusbaum, Stein, Goldstein, Bronstein & Kron
20 Commerce Boulevard, Suite E
Succasunna, New Jersey 07876-1348

In re: Chaya Morganstern and Menachem Grossbaum

Dear Mr. Stein,

I have sent you my curriculum vita under separate cover. As you know I was the Medical Director and the Director of DNA Laboratory at Reproductive Genetics Institute in Chicago from May, 1988 to October, 2000. As such I was a pioneer in the field of preimplantation genetic diagnosis (PGD) and am the first author on the first publication describing preimplantation diagnosis for Cystic Fibrosis appearing in the journal *Lancet* in 1990. As such I consider myself to be an expert in the field of PGD.

I have reviewed the materials you sent me regarding this case and have reached some conclusions regarding the appropriateness of care in this case. Before I go into the conduct of this case, I would like to point out a clear factual inaccuracy that I have discovered that may have bearing on the integrity of defendants in this action.

In the deposition from Mark Hughes dated February 19, 2009, on page 18, lines 23 and 24, he states in response to a question regarding PGD, "…it's been going on since I invented the technology, 19 years ago." Mark Hughes did not invent PGD. The initial publication describing PGD was from Alan Handyside et al that appeared in the journal *Nature* in 1990. The first description of PGD for Cystic Fibrosis or for any other single gene disorder was published by my group that same year (see above). In no way can Mark Hughes justify the claim that he invented this technology. In fact Mark Hughes attended a workshop that we hosted where we taught PGD techniques to those wanted to learn them.

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Now to the specifics of the case. Chaya Morganstern-Grossbaum and Menachem Grossbaum presented for PGD to the NYU fertility center. Routine CF carrier detection had determined that Chaya Grossbaum was a carrier of the mutation G542X and Menachem was a carrier for delta F508. Thus this couple was at a 25% risk of having a child affected with CF. The situation in which each parent carries a different CF mutation is technically referred to compound heterozygosity. At the time this couple presented they should have been informed that this particular situation is extremely risky when performing PGD on blastomere biopsies because of a well known phenomenon known as allele drop out (ADO). In every cell there are 2 copies of the CF gene. When analyzing a single cell, it is well known that sometimes one of the 2 genes is not amplified by the PCR reaction and therefore it not analyzed in the diagnostic procedure. ADO has a much higher rate in blastomeres than polar bodies that are the other material being used for PGD at this time. So when each parent carries a different mutation, the blastomere will ALWAYS contain at least one copy of the normal gene. So there is no way to be sure whether a blastomere whose analysis shows only the normal gene actually is a blastomere with 2 normal copies of the CF gene or actually has one normal copy and one mutant gene that has suffered from ADO and therefore hasn't been identified. Since ADO rates in blastomeres has been shown by many authors to be at least 20% (and some authors have shown as high as 70%), the PGD on blastomeres in couples with compound heterozygosity has an unacceptably high error rate.

Thornhill and Snow write in a review of PGD "…for compound heterozygous or autosomal dominant conditions, the consequences of ADO can be catastrophic, as misdiagnosis and subsequent transfer of affected embryos can occur."

Because of this inherent difficulty with PGD performed on blastomeres in compound heterozygous couples, two methods were developed to improve diagnostic accuracy. The first is the use of linked markers to detect ADO when it occurs in order to prevent misdiagnosis. We have shown that the use of 1 linked marker reduces the undetected ADO rate approximately 50% and the use of 3 linked markers virtually eliminates misdiagnosis due to undetected ADO. For this couple, in order to develop an assay incorporating linked markers, other family members would have had to be studied in order to determine the haplotypes of the CF mutations. This would have involved collecting samples from siblings and / or parents of Chaya and Manachem. There is no evidence that this was suggested or offered as a possibility.

A second method to reduce diagnostic errors in this situation is to perform the PGD on polar bodies rather than on blastomeres. The ADO rate in polar bodies is approximately 5 fold less than in is blastomeres. In addition, due to a phenomenon called crossing over, approximately 50% of first polar bodies are heterozygous, eliminating the possibility of a misdiagnosis due to ADO altogether. Linked markers could have been incorporated into the polar body diagnosis also thereby further reducing the possibility for diagnostic errors. Both these alternatives were available at the time from Reproductive Genetics Institute in Chicago.

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There is no evidence that this couple was offered either of these alternative procedures which would have greatly reduced the opportunity for diagnostic error. Simply telling the couple "this is a research procedure" or this is "imperfect" ignores the fact that there were two alternative procedures available at the time that afforded a much higher likelihood of diagnostic accuracy that were not presented to the family.

In the unlikely event that a compound heterozygous couple was presented with the alternatives and still insisted on going forward with PGD by blastomere biopsy without using linked markers the couple should have been informed that the potential for misdiagnosis varies with the apparent genotype of the embryo.

The lowest risk of a misdiagnosis would be in an embryo that appeared to inherit only the normal alleles from both parents. In this situation an affected child could be born only if ADO occurred during the analysis of both mutations. Since the likelihood of ADO occurring in a single mutation analysis in a blastomere is approximately 25% the probability of having ADO occur simultaneously for two mutations in the same blastomere analysis is 25% (0.25) multiplied by 25% (0.25) or 6.2%. Thus the chances of an embryo being affected when both mutation analyses are successful and both showing normal genes only would be 6.2%. Unfortunately no single embryo in this case showed that result.

The embryos transferred in this case were numbers 7 and 8.

Embryo 7 had no result for the father's mutation and an apparent normal allele for the mother's mutation. The failure to obtain analysis for the paternal mutation indicates that the DNA from this blastomere was at least partially degraded making the likelihood of ADO in the analysis of the maternal allele even higher than the 25% I quote to my patients. Since there are no results for the paternal allele, I would estimate the chances of this embryo being affected with CF to be at least 15% - 20% and probably higher.

The analysis for Embryo 8 demonstrated that the blastomere contained the mutant maternal CF allele and the analysis of the paternal allele revealed apparently normal results. However, given an ADO rate of 25%, the chances of this embryo being affected are approximately 25%.

Thus the 2 embryos transferred both had risks of being affected which is similar to the priori risk of 25% for any couple who are carriers for a recessive genetic disease without any PGD performed. Thus the chances of this couple having an affected child following the expensive procedure are similar to their chances of having an affected child if nothing was done.

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There is no evidence that this couple was told of these chances for misdiagnosis. These embryos should only have been transferred with documentation that the parents were informed about the significant risks of having an affected embryo transferred.

There is a long discussion in the deposition of Mark Hughes as to the requirements for every couple undergoing PGD to have an invasive prenatal diagnostic procedure. In fact, Mark Hughes mentioned that he would have refused to do the case if he had known the couple would not have had a prenatal diagnosis. He states that the reason for this is for quality assurance purposes only and not for the purposes of pregnancy termination. This is belied by the facts. Quality Assurance can be obtained by testing umbilical chord blood at the time of delivery if a couple has eschewed a prenatal diagnosis. In fact no effort was made to determine the results of any prenatal diagnosis since Mark Hughes, by his own admission, was not aware that the couple had not had a prenatal diagnosis. The lab also obviously made no effort to obtain umbilical chord blood or a peripheral blood sample.

The notification that the Grossbaum's baby was affected with CF came not at the instigation of the laboratory but from a phone call from some unidentified person in New York. In fact the lab actually believed twins were born when it was a singleton birth. The failure to follow-up on the results of PGD shows a stunning lack of Quality Assurance in the laboratory. If the only reason they were aware an affected child was born was an anonymous phone call, how many other misdiagnoses have occurred that they are not aware of?

Most couples requesting PGD do so because they are opposed to option of prenatal diagnosis with subsequent termination of affected fetuses. The reasons behind this may by religious belief, ethical stance, or emotional trauma due to previous instances of terminating affected fetuses. If a couple such as the Grossbaum's were in religious opposition to abortion, the only reason for them to have an invasive prenatal diagnostic procedure would be either reassurance (if the prenatal diagnosis showed an unaffected child) or preparedness (should the prenatal diagnosis reveal an affected child). Invasive prenatal diagnosis either by CVS or amniocentesis carries risks of miscarriage so the choice of refusing a prenatal diagnostic procedure was a reasonable and understandable decision by this couple. Since they would not have terminated an affected fetus anyway, even if they had elected to have a prenatal diagnosis would not have prevented the birth of an affected child because of their religious prohibition of abortion.

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In 2004, the state of PGD was in such an advanced state that with competent laboratory practice (using linked markers with or without polar body), coercing someone into having a prenatal diagnostic procedure against their will in order to qualify for PGD is distasteful at best and abusive at worst.

I am also concerned about the informed consent process. I see a form entitled "Pre-Case Phone Review of PDG Informed Consent" dated 03/25/2004. This seems to be notes from a telephone conversation between Mark Hughes and the Grossbaum's. However the signed informed consent is dated 6/4/2004, 71 days later. The informed consent is witnessed, signed and dated 6/4/2004 by the Grossbaum's and a witness with an unrecognizable signature. The signature line for the principal investigator is signed Mark Hughes but dated 7/16/04, 35 days later. The pertinent question is who actually obtained the informed consent and was this individual competent to answer all questions and re-explain all procedures since PGD is complex and 71 days had passed between the initial telephone counseling session and the signing of the informed consent.

I am reproducing 2 paragraphs from the federal register pertinent to this point. These are direct quotes from ***21 CFR 50.25 Elements of informed consent.*** This document is available at: http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm116333.htm

"The clinical investigator is responsible for ensuring that informed consent is obtained from each research subject before that subject participates in the research study. FDA does not require the investigator to personally conduct the consent interview. The investigator remains ultimately responsible, even when delegating the task of obtaining informed consent to another individual knowledgeable about the research....
The IRB should be aware of who will conduct the consent interview. The IRB should also be informed of such matters as the timing of obtaining informed consent and of any waiting period (between informing the subject and obtaining the consent) that will be observed."

These regulations require notification to the Institutional Review Board (IRB) if there is a waiting period between informing the subject and obtaining the consent. Was the notification made? Alternatively if the entire consent process was recreated on 6/4/2004 who administered the informed consent, how knowledgeable is that individual with respect to PGD, and was the IRB notified that this individual was conducting the informed consent process.

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In my opinion the care given to the Grossbaum's was clearly well below acceptable standards. The couple was not given the opportunity to select a more accurate procedure than the one they were offered. There was no discussion of the risks of using blastomere biopsy without linked markers in a compound heterozygous situation. The fault was clearly on the part of Mark Hughes since he provided the expert consultation and administered the informed consent to the patient. Whether or not NYU has culpability because they trusted that their patients were receiving adequate care from Genesis Genetics, the self proclaimed inventors of PGD, is open for discussion.

Respectfully submitted.

Charles M. Strom, M.D., Ph.D., F.A.A.P., F.A.C.M.G., H.C.L.D.
Medical Director, Genetic Testing Center
Quest Diagnostics Nichols Institute

EXHIBIT 26

Contraception. 2008 Jan;77(1):10-21. Epub 2007 Dec 3.

Estimates of contraceptive failure from the 2002 National Survey of Family Growth.

Kost K, Singh S, Vaughan B, Trussell J, Bankole A.

Guttmacher Institute, New York, NY 10038, USA. kkost@guttmacher.org

Comment in:

Contraception. 2008 Jul;78(1):85.

Abstract

BACKGROUND: In 2001, the US government's "Healthy People 2010" initiative set a goal of reducing contraceptive failure during the first year of use from 13% in 1995 to 7% by 2010. We provide updated estimates of contraceptive failure for the most commonly used reversible methods in the United States, as well as an assessment of changes in failure rates from 1995 to 2002.

STUDY DESIGN: Estimates are obtained using the 2002 National Survey of Family Growth (NSFG), a nationally representative sample of US women containing information on their characteristics, pregnancies and contraceptive use. We also use the 2001 Abortion Patient Survey to correct for underreporting of abortion in the NSFG. We measure trends in contraceptive failure between 1995 and 2002, provide new estimates for several population subgroups, examine changes in subgroup differences since 1995 and identify socioeconomic characteristics associated with elevated risks of failure for three commonly used reversible contraceptive methods in the United States: the pill, male condom and withdrawal.

RESULTS: In 2002, 12.4% of all episodes of contraceptive use ended with a failure within 12 months after initiation of use. Injectable and oral contraceptives remain the most effective reversible methods used by women in the United States, with probabilities of failure during the first 12 months of use of 7% and 9%, respectively. The probabilities of failure for withdrawal (18%) and the condom (17%) are similar. Reliance on fertility-awareness-based methods results in the highest probability of failure (25%). Population subgroups experience different probabilities of failure, but the characteristics of users that may predict elevated risks are not the same for all methods.

CONCLUSION: There was no clear improvement in contraceptive effectiveness between 1995 and 2002. Failure rates remain high for users of the condom, withdrawal and fertility-awareness methods, but for all methods, the risk of failure is greatly affected by socioeconomic characteristics of the users.

PMID: 18082661 [PubMed - indexed for MEDLINE] PMCID: PMC2811396 **Free PMC Article**

Obstet Gynecol. 1999 Jun;93(6):896-903.

Contraceptive effectiveness of two spermicides: a randomized trial.

Raymond E, Dominik R.

Family Health International, Research Triangle Park, North Carolina 27709, USA. eraymond@fhi.org

Abstract

OBJECTIVE: We conducted a multinational randomized trial to determine whether a spermicidal film containing 72 mg of nonoxynol-9 per film was at least as effective in preventing pregnancy as a foaming tablet containing 100 mg of nonoxynol-9 per tablet.

METHODS: Between September 1995 and July 1997, 765 women aged 18-35 years who had no evidence of subfecundity were randomly assigned to use one of the two spermicides as their only contraceptive method at every coital act for 28 weeks. Participants were asked to keep coital diaries throughout the study period. Pregnancy tests were performed on a scheduled basis. Each participant was followed for 28 weeks or until she stopped considering the spermicide as her primary method of contraception.

RESULTS: The Kaplan-Meier estimate of the 6-month probability of pregnancy during typical use of the spermicide was 28.0% in the tablet group and 24.9% in the film group (P = .78, one-tailed test). The study had nearly 75% power to have detected a difference of seven percentage points between groups. Results were almost identical when the analysis included only months when the participants reported use of the spermicide during every coital act. Reported levels of sexual activity and compliance with use of the spermicide were high in both groups.

CONCLUSION: The contraceptive effectiveness of these two spermicidal products appeared similar. Both products were associated with a fairly high risk of pregnancy in this young, highly sexually active population.

PMID: 10362151 [PubMed - indexed for MEDLINE]

PubMed

U.S. National Library of Medicine
National Institutes of Health

Display Settings: Abstract

Obstet Gynecol. 2004 Mar;103(3):430-9.

Contraceptive effectiveness and safety of five nonoxynol-9 spermicides: a randomized trial.

Raymond EG, Chen PL, Luoto J; Spermicide Trial Group.

Family Health International, PO Box 13950, Research Triangle Park, NC 27709, USA. eraymond@fhi.org

Abstract

OBJECTIVES: To estimate and compare the effectiveness and safety of 5 spermicides over 6 and 7 months of use, respectively. The spermicides included 3 gels containing 52.5 mg, 100 mg, and 150 mg of nonoxynol-9 per dose and a film and a suppository, each containing 100 mg of nonoxynol-9 per dose.

METHODS: Women wishing to use only spermicide for contraception for 7 months were randomly assigned to use 1 of the 5 spermicides with emergency contraception backup. Participants were followed up for up to 30 weeks after admission.

RESULTS: Of 1,536 women enrolled, 868 (57%) either relied on the spermicide for 6 months or became pregnant. The probability of pregnancy during 6 months of typical use of the spermicide was 22% (95% confidence limits 16%, 28%) in the 52.5-mg gel group, 16% (10%, 21%) in the 100-mg gel group, 14% (9%, 19%) in the 150-mg gel group, 12% (7%, 17%) in the film group, and 10% (6%, 15%) in the suppository group. The pregnancy risk in the 52.5-mg gel group was significantly different ($P < .05$) from that in either of the other gel groups. The pregnancy risks in the three 100-mg product groups were not significantly different ($P = .35$). No significant differences among groups were found in the 7-month probability of specified urogenital conditions.

CONCLUSION: The gel with the lowest amount of nonoxynol-9 was less effective than the 2 higher-dose gels. Among 3 products containing 100 mg of nonoxynol-9, formulation did not significantly affect pregnancy risk. All products were safe.

LEVEL OF EVIDENCE: I

PMID: 14990402 [PubMed - indexed for MEDLINE]

Publication Types, MeSH Terms, Substances, Grant Support

LinkOut - more resources

EXHIBIT 27

2981.101 206

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
DOCKET NO. 07-CV-1359

CHAYA GROSSBAUM and MENACHEM GROSSBAUM, her spouse, individually and as guardians ad litem of the infant, ROSIE GROSSBAUM,

Plaintiffs,

vs.

GENESIS GENETICS INSTITUTE, L.L.C., of the State of Michigan, MARK R. HUGHES, M.D., NEW YORK UNIVERSITY SCHOOL OF MEDICINE and NEW YORK UNIVERSITY HOSPITALS CENTER, both corporations in the State of New York, ABC CORPORATIONS 1-10 and JOHN DOE 1-10,

Defendants.

DEPOSITION OF:

CHAYA GROSSBAUM
(VOL. 2)

COPY

B E F O R E: NANCY J. GILMARTIN, a Certified Shorthand Reporter and Notary Public of the State of New Jersey at the office of NUSSBAUM, STEIN, GOLDSTEIN, BRONSTEIN & KRON, ESQS., 20 Commerce Boulevard, Succasunna, New Jersey, on Thursday, March 12, 2009, commencing at 10:55 a.m., Pursuant to Notice.

GILMARTIN COURT REPORTING SERVICE
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APPEARANCES:

NUSSBAUM, STEIN, GOLDSTEIN, BRONSTEIN & KRON, ESQS.
BY: LEWIS STEIN, ESQ.
For the Plaintiffs

STEPHEN N. LEUCHTMAN, P.C.
BY: STEPHEN N. LEUCHTMAN, ESQ.
For the Defendants Genesis Genetics Institute, L.L.C. and Dr. Hughes

MARSHALL, DENNEHEY, WARNER, COLEMAN & GOGGIN, ESQS.
BY: R. SCOTT EICHHORN, ESQ.
For the Defendants New York University School of Medicine and New York University Hospitals Center

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EXHIBITS

CHAYA GROSSBAUM,
97 Mill Street, Morristown, New Jersey,
having duly affirmed, testified as
follows:

DIRECT EXAMINATION BY MR. EICHHORN:

Q Good morning, Mrs. Grossbaum. We are back here again at your lawyer's office to complete the deposition which we started on December 17th. Okay?

A Okay.

Q You were placed under oath that day. You were just placed under oath again. I went through a series of instructions with you at the beginning last time, and do you remember -- I mean, I deposed you and Mr. Leuchtman asked some questions, for the better part of the day you were answering questions, but as you sit here now in March, do you remember those instructions?

A Yes.

Q Are you comfortable going forward without me repeating them because I'm happy to repeat them if you'd like?

A I'm comfortable going forward.

MR. EICHHORN: Okay. At the end of

the deposition -- and actually I'm saying this more to you, Lou -- at the end of the deposition last time we agreed that I would not ask -- that we were finished on liability.

MR. STEIN: Right. That's correct.

MR. EICHHORN: And we were. I do, however, have a couple questions I would like to ask her to finish up liability. So I'd like to get them out of the way first. It's five minutes, probably less.

MR. STEIN: Well, you know, again, I recognize that we all don't have the advantage of going back after we read a transcript and decide that we'd like to cross-examine the witness further. I frequently do, so, you know, can you tell me what area of inquiry you intend to go into so I can make any objection in that regard as I deem it appropriate?

MR. EICHHORN: Yes, I will, and I think it's actually a very significant question that I intend to ask her. You know, there's a model jury charge that applies to cases like this, and it talks about the law in this setting. And I want to ask her questions, just a couple actually, that help -- what's the word? -- make

care. They wait until like a couple of months I think, a few months until you start getting regular prenatal care.

Q Let me ask you this: At what point in your pregnancy did you start with Midwives of Denville?

A I believe I was a couple of months pregnant.

Q So can you tell me about how long you continued to follow with NYU until they determined it was a viable pregnancy?

A I believe it was six weeks.

Q Six weeks. Okay. I misunderstood your earlier answer.

And during those six weeks, how were you monitored, with ultrasound?

A Ultrasounds and blood work to check hormone levels. I had to continue taking progesterone injections.

Q Then from once you began with Midwives of Denville, was your interaction with NYU completed?

A Yes.

Q And your pregnancy, was it, from your perspective as a patient, was it uneventful

or did you have any particular difficulties?

A It was uneventful.

Q What testing, if any, did you undergo during your pregnancy after you were completed with NYU?

A All the blood work that's required, the diabetes testing, the urine testing that they do. I think I did one or two ultrasounds or whatever. Yeah, all the basic tests.

Q And you gave birth to Rosie at what hospital?

A St. Clare's in Denville.

Q Was that a normal spontaneous vaginal delivery?

A Yes.

Q Any complications with it?

A No.

Q How long were you in the hospital?

A I gave birth Friday and I went home on Sunday.

Q And am I correct you didn't have any physical problems as a result of it?

A No.

Q And how about Rosie, how long was she at St. Clare's?

A Same time.

Q So Friday, discharged Sunday you said?

A Yes.

Q When did you learn that Rosie had cystic fibrosis?

A When she was about two weeks old.

Q And please tell me what happened that you learned that at that time.

A The state does testing in the hospital, and we got a letter stating that they weren't happy; that we should go see our doctor because there was -- the results showed that she possibly had, you know, one of these issues. So we -- at the same time the doctor got the letter and he also contacted us and we contacted him.

Q When you say "one of these issues," was it a form letter that gave a whole lot of different --

A Yeah.

Q And CF was one of them?

A Yes.

Q Was there a check next to CF or did it just give a list and it said your child may have one of these?

A I don't remember.

Q Do you have that letter still?

A I don't think so.

Q You said the state does testing. Was the letter from the state or was the letter from the hospital?

A I don't remember.

Q And it said that your child may have one of these things or did have one?

A I don't remember the exact wording.

Q But, in any event, it recommended that you see your doctor?

A Yeah. And I believe they also sent the letter to the pediatrician.

Q And who was the pediatrician?

A Dr. Richard Dicker.

Q So did you contact Dr. Dicker or did his office contact you about this issue?

A I contacted him, and at the same time I believe he was also trying to contact us.

Q So, in any event, you contacted each other somehow and I guess you brought Rosie in to see him?

A We brought Rosie -- he sent us I believe directly to Dr. Atlas.

EXHIBIT 28

genesis
genetics institute

PAID
6-3-04

INVOICE

DATE: July 27, 2004

Bill To:
Chaya Morgenstern
763 East End Pkwy # 84
Brooklyn, NY 11213

For:
PGD Services
Morganstern-Grossbaum.M/C.CF10+11.Grifo-NYU.2004#316

DESCRIPTION	AMOUNT
Cycle #1 Laboratory Testing	
Registration, Phone coordination, Receipt & Processing of blood samples into cells and the isolation/purification of genomic DNA. Genetic pre-case analysis.	
Design, development, construct & optimize unique molecular, fluorescent oligonucleotide DNA probes. Test single blastomeres submitted from biopsy. Interpret data, produce report.	
Total Capped Maximum Charges (per Dr. Hughes)	$ 2,500.00
Courier delivery of samples to Genesis Genetics Institute	250.00
Please remit promptly so that we may continue to keep the costs for PGD as inexpensive as possible for other couples like you.	
It has been our pleasure working with you and your IVF center in helping you build a healthy family.	
TOTAL	$ 2,750.00

Make all checks payable to **Genesis Genetics Institute**
If you have any questions concerning this invoice please call Kate at 544.4006

THANK YOU FOR YOUR BUSINESS!

1380 E. Jefferson
Detroit, MI 48207
313.544.4006

EXHIBIT 29

From: Shannon Wiltse
To: rochiegrossbaum@hotmail.com
Date: Saturday - May 22, 2004 10:07 PM
Subject: Morganstern-Grossbaum.M/C.CF10+11.Grifo

Dear Mrs. Grossbaum,
Here is the information you requested regarding payment:

The check can be made out to Genesis Genetics.
The bill is as follows:
$2500 for the PGD
$250 for the Marken Courier Service
Total: $2750.00

Checks can be mailed to
Genesis Genetics
1380 East Jefferson Ave.
Detroit, MI. 48207

Thank you,
Shannon Wiltse, MS, CGC
Genetic Counselor
Genesis Genetics Institute

From: Shannon Wiltse
To: pgd@genesisgenetics.org
Date: Saturday - May 22, 2004 10:03 PM
Subject: Morganstern-Grossbaum.M/C.CF10+11.Grifo-NYU.2004#316

Hi Dr. Hughes,
This patient already had a conference call with you and is planning for PGD in July after vacation.

Shannon

5/22/04
Spoke with Mrs. Grossbaum. She already had a phone consult with Dr. Hughes and they are planning on doing PGD in July. She wants me to let her know what the bill is. Her e-mail is rochiegrossbaum@hotmail.com

5/22/04
Left message at home number. Dr. Hughes wants to know if they had a conference call. Otherwise we are set to go.

From: "Shannon Wiltse" <swiltse@genesisgenetics.org>
Sent: Tue, January 25, 2005 8:47 am
To: griolf01@med.nyu.edu
Subject: Morganstern-Grossbaum.M/C.CF10+11.Grifo-NYU.2004#316

Hi Fran,
I am doing some more follow-up. Do you know if Chaya Morganstern-Grossbaum got pregnant from her July 2004 cycle? If so, is it a singleton, twins, etc.?

Thank you,
Shannon Wiltse, MS, CGC
Genetic Counselor
Genesis Genetics Institute

From: " Shannon Wiltse
To: Rochle Grossbaum" <rochiegrossbaum@hotmail.com>
Date: Tuesday - June 2, 2004
Subject: RE: Morganstern-Grossbaum.M/C.CF10+11.Grifo

Dear Chaya,
We will watch for the check.

Thank you,
Shannon

From: "Rochle Grossbaum" <rochiegrossbaum@hotmail.com>
To: Shannon Wiltse
Date: Tuesday - June 1, 2004 10:41 PM
Subject: RE: Morganstern-Grossbaum.M/C.CF10+11.Grifo

Dear Shannon,
I just wanted to let you know that I sent the check for $2750.00 out today and you should be receiving it soon.

Thank you,